EXHIBIT 30

RULES and REGULATIONS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5 and 101

(Docket Nos. 91N-0384 and 84N-0153)

RIN 0905-AD08 and 0905-AB68

Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food

Wednesday, January 6, 1993

***2302** AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its food labeling regulations to: (1) Provide definitions for specific nutrient content claims using the terms "free," "low," "lean," "extra lean," "good source," "high," "reduced," "light" or "lite," "less," "fewer," and "more" and provide for their use on the food label; (2) provide for the use of implied nutrient content claims; (3) define and provide for the use of the term "fresh;" and (4) address the use of the terms "natural" and "organic." This action is part of the food labeling initiative of the Secretary of Health and Human Services (the Secretary) and in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments).

EFFECTIVE DATE: February 14, 1994, except §§ 101.10 and 101.13(q)(5) concerning restaurant firms consisting of 10 or less individual restaurant establishments for whom these sections will become effective on February 14, 1995.

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SUPPLEMENTARY INFORMATION:

I. Introduction

A. Background

In the Federal Register of November 27, 1991 (56 FR 60421), FDA published a proposed rule (entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms" hereinafter referred to as the general principles proposal) to: (1) Define nutrient content claims (also known as descriptors) and to provide for their use on foods labels; (2) define specific nutrient content claims that include the terms "free," "low," "source," "reduced," "light" or "lite," and "high"; (3) provide for comparative claims using the terms "less," "fewer," and "more"; (4) set forth specific requirements for sodium and calorie claims; (5) establish procedures for the submission and review of petitions regarding the use of nutrient content claims; (6) revise § 105.66 (21 CFR 105.66), to solely cover foods for special dietary use in reducing or maintaining body weight; (7) establish criteria for the appropriate use of the term "fresh;" and (8) address the use of the term "natural." A document correcting various editorial errors in that proposed rule was published in the Federal Register of March 6, 1992 (57 FR 8189).

In the same issue of the Federal Register (56 FR 60478), FDA also published a proposed rule (entitled "Food Labeling: Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food" hereinafter referred to as the fat/cholesterol proposal) to define and provide for the proper use of the nutrient content claims "fat free," "low fat," "reduced fat," "low in saturated fat," "reduced saturated fat," "cholesterol free," "low cholesterol," and "reduced cholesterol." A document correcting various editorial errors in the fat/cholesterol proposal was also published in the Federal Register of March 6, 1992 (57 FR 8177). The agency published the fat/cholesterol proposal as a separate document from the general principles proposal, even though it had based the two documents on the same statutory provisions, because it had published a tentative final rule on cholesterol content claims in the Federal Register of July 19, 1990 (55 FR 29456). FDA included proposed definitions for fat and fatty acid content claims in the fat/cholesterol proposal because of the interrelationship among these nutrients and cholesterol in the etiology of cardiovascular disease.

Also in the same issue of the Federal Register (56 FR 60507), FDA published a proposed rule (entitled "Food Labeling: 'Cholesterol Free,' 'Low Cholesterol,' and '——— Percent Fat Free' Claims") to define "cholesterol free" and "low cholesterol" and to provide for the proper use of these terms and the term "——— percent fat free." The proposed rule was intended to ensure on an interim basis that these terms are not used in a manner that is misleading to consumers.

The general principles proposal (56 FR 60421) and the fat/cholesterol proposal (56 FR 60478) were issued as part of the agency's food label reform initiative and in response to the 1990 amendments (Pub. L. 101-535). The food label reform began in 1989 when FDA published an advance notice of proposed rulemaking (ANPRM) that announced a major initiative concerning the use of food labeling as a means for promoting sound nutrition. The following year (November 8, 1990), the President signed the 1990 amendments into law. This legislation clarified and strengthened FDA's legal authority to require nutrition labeling on foods and to establish those circumstances whereby claims can be made about nutrients in foods. Now as FDA prepares to implement the new regulations, the agency reiterates that the 1990 amendments have three basic objectives. They are: (1) To make available nutrition information that can assist consumers in selecting foods that can lead to healthier diets, (2) to eliminate consumer confusion by establishing

definitions for nutrient content claims that are consistent with the terms defined by the Secretary, and (3) to encourage product innovation through the development and marketing of nutritionally improved foods. With these goals in mind, the agency believes that the new regulations will reestablish the credibility of the food label.

With respect to nutrient content claims, the 1990 amendments amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 403(r)(1)(A) of the act (21 U.S.C. 343(r)(1)(A)) which states that a food is misbranded if it bears a claim in its label or labeling that either expressly or implicitly characterizes the level of any nutrient of the type required to be declared as part of the nutrition labeling, unless such claim is made in accordance with section 403(r)(2).

The agency received over 1,800 comments in response to the general principles proposal, and 500 comments in response to the fat/cholesterol proposal. Each comment addressed one or more of the provisions in these proposals. The comments were from a variety of sources including consumers, health care professionals, trade organizations, manufacturers, consumer advocacy organizations, foreign governments, and State and local governments. Many of the comments generally agreed with one or more provisions of the proposal, without providing other grounds for support other than those provided by FDA in the preamble to the proposal. Several comments addressed issues covered by other proposals that are a part of this overall food labeling initiative and will be addressed in those final documents, while other comments addressed issues ***2303** outside the scope of the proposal and will not be discussed here.

A number of comments to the general principles and fat/cholesterol proposals suggested modifications in, or were opposed to, various provisions of the proposals. Because the general principles governing both documents are identical, and because the issues raised in comments responding to the two proposals are similar, FDA has chosen to address the comments on, and to establish regulations based on, both proposals in this single document. The agency will summarize the issues raised in the comments and address them in this document.

The agency also notes that it received about 125 comments on the tentative final rule on cholesterol content claims after the closing date for comments of August 20, 1990. These comments were not addressed in the fat/cholesterol proposal. However, the agency has reviewed these comments and is also responding to them in this final rule.

As for the third proposal on cholesterol claims and "——— percent fat free," FDA has concluded that this final rule will provide adequate assurance to consumers that these terms are not used in a misleading manner. Therefore, the agency is announcing that it is withdrawing this proposal. Comments that were submitted on this proposal (Docket No. 84N-153A) have been considered in the development of this final rule. They will be addressed with the other comments on the general principles proposal and the fat/cholesterol proposal in this final rule.

B. Foods for Special Dietary Use

In 1978, FDA promulgated regulations in § 105.66 pertaining to the use of the terms "low calorie" and "reduced calorie" on foods represented as or purporting to be for special dietary use in the maintenance or reduction of caloric intake or body weight. Under the 1990 amendments, FDA is defining the terms "low" and "reduced" as nutrient content claims that identify the level of a nutrient in a food intended for consumption by the general population and is adopting specific definitions for the terms "low calorie" and "reduced calorie." To reflect these actions, the agency is revising § 105.66 to delete the provisions that define "low calorie" and "reduced calorie." Because § 105.66 was

6. Modified

218. Of those commenting on the term "modified," most agreed with the proposed use of the term. However, one comment stated that the term "modified" does not explain whether the nutrient has been reduced or augmented. Another comment suggested that the word "modified" used to compare dissimilar products would be misleading and recommended that foods bearing the term "modified" as part of the statement of identity not be allowed to use a dissimilar food as reference food. It said that a food labeled "modified" should be required to be actually changed as compared to other foods of its type. A few comments said that "modified" should be used only to distinguish chemical changes in a food or to refer to the nutrient character of the food (e.g., "modified fat" or "modified food starch"), not to a change in the amount of a nutrient. A comment suggested that "adjusted" should be used instead of "modified." Another comment suggested that the term "modified" was unattractive for marketing purposes.

The agency points out that the term "modified" is not meant to be used alone, nor was the term meant to be used to describe products that had not been altered. Therefore, as discussed in comment 204 of this document, the term will not be permitted based on a comparison to a dissimilar product.

Additionally, because the word "modified" reflects a change in the food, the reference food used for the "modified" would be one that was appropriate for a "reduced" or "added" claims. For example, a modified fat cheddar cheese would have as its reference a full fat version of cheddar cheese, not some other cheese.

The comment suggesting "adjusted" did not provide any basis to believe that this term is more useful as part of the statement of identity to reflect a change in a food than is the term "modified." In addition, the agency is not persuaded that the term "modified" is an inappropriate term to reflect nutrient changes in a food, or that it should be limited only to uses describing changes in the chemical nature of a food or in the character of the food, such as "modified food starch." Accordingly, the agency is not amending its provision ***2368** for the term "modified" and is retaining the criteria as proposed in § 101.13(k).

D. Implied Claims

In the general principles proposal (56 FR 60421 at 60423), FDA proposed to define an implied nutrient content claim as any claim that describes the food or an ingredient therein in such a manner that leads a consumer to assume that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"), or that the food because of its nutrient content, may be useful in achieving a total diet that conforms to current dietary recommendations (e.g., "healthy"). The agency stated that, under the provisions of the statute, such implied claims are prohibited until they are defined by FDA by regulation.

However, the agency recognized that an argument could be made that statements such as "contains oat bran" are not intended to be nutrient content claims but are intended to advise consumers about the nature of certain ingredients. Likewise, the agency said that statements that a particular ingredient constitutes 100 percent of the food, e.g., "100 percent corn oil," should not be considered implied nutrient content claims when such statements are the statement of identity for the food. Moreover, the agency reasoned that claims such as "contains no preservatives" could not be

characterized as nutrient content claims because they do not relate to nutrients of the type addressed in nutrition labeling.

The agency requested comments on how to draw an appropriate line between implied nutrient content claims and ingredient and other label claims. The agency did not propose regulations that authorized specific implied claims. However, it solicited comments concerning criteria for evaluating whether implied claims are appropriate and not misleading, as well as information on specific implied claims. The agency said that if it received sufficient information in comments, it would consider providing for specific implied claims in the final regulation. The agency said that, alternatively, it would defer action on implied claims until after the rulemaking required by the 1990 amendments is complete and would then consider individual implied claims through the petition process on a case-by-case basis.

1. General

219. The agency received a wide variety of comments on what should constitute an implied nutrient content claim, and on what steps the agency should take to regulate such claims. Some comments stated that FDA must maintain strict control of claims made on food labels in order to prevent misleading nutrient content claims and subsequent consumer confusion. Another comment stated that the agency should develop a list of acceptable implied nutrient content claims and accept others on a petition basis. Several comments asserted that the proposed regulations are too vague and will not allow manufacturers to determine whether or not an ingredient claim will be considered an implied nutrient content claim by the agency. Some of these comments stated that because of the vagueness of provisions that rely on interpreting consumer perception and the criminal nature of violations of the act, it is incumbent on the agency to define with specificity, and through rulemaking, the standards by which implied claims will be judged. Other comments provided a wide variety of suggestions, discussed in detail below, as to what should constitute an implied nutrient content claim, what should not constitute such a claim, and what, if any, implied nutrient content claims should be provided for in regulations.

Other comments suggested that factual statements, particularly ingredient statements, that constitute implied claims and that are found to be misleading should be regulated under the general misbranding provision of section 403(a) of the act. One of these comments asserted that whether a label statement is an implied nutrient content claim can only be determined on a case-by-case basis in which the context of the entire label is considered. The comment stated that it is highly implausible to identify specific words that will always constitute implied claims. Some comments supported such a case-by-case approach on the grounds that a blanket prohibition of ingredient claims that constitute implied nutrient content claims would prohibit the presentation of truthful labeling statements concerning the content of a food product. Another comment stated that affording manufacturers wide latitude in language would better serve to educate consumers about nutrition and the nutrient content of food, because they would not become bored with and disregard a limited number of repetitive descriptors.

The agency disagrees with those comments that said that implied claims should be prohibited and also with those that suggested that all implied claims should be regulated under section 403(a) instead of 403(r) of the act. The language of the statute and the legislative history make clear that implied nutrient content claims are subject to the nutrient content claims regime. Section 403(r)(1)(A) of the act provides that a food is misbranded if it bears a claim that "expressly or by implication characterizes the level" of a nutrient unless the claim is made in accordance with regulations estab-

lished by FDA. Section 3(b)(1)(A)(i) of the 1990 amendments instructs the agency to establish regulations that identify claims described in section 403(r)(1)(A) of the act that comply with section 403(r)(2). The legislative history (H. Rept. 101-538, supra 19) includes reference to "high in oat bran" as an example of an implied nutrient content claim. This reference to an ingredient claim as an implied claim subject to section 403(r)(1)(A) of the act clearly demonstrates that Congress intended that at least some statements about ingredients be subject to regulation under section 403(r)(1)(A). Accordingly, FDA concludes that it must attempt to define implied nutrient content claims.

The agency examined the comments carefully in attempting to devise a scheme for determining when a label statement is an implied nutrient content claim. The agency agrees with the comment that stated that in many cases whether a label statement is an implied nutrient content claim can only be evaluated on a case-by-case basis, considering the entire label and the context within which the claim is made. However, FDA also agrees with the comments that the definition in proposed § 101.13(b)(2) is too vague. Accordingly, as discussed below, FDA has modified that definition. Moreover, FDA has identified groups of claims that it concludes can be defined and would not be misleading. The agency is providing in new § 101.65(c) definitions for these claims.

However, because of the large variety of statements that can be considered to be implied claims, because of resource constraints, and because of the strict timeframes under which this rulemaking has been accomplished, FDA is unable to adopt a comprehensive set of implied nutrient content claims. Interested persons may provide information to the agency with which it can develop additional definitions, or they may submit petitions requesting approval of specific definitions or brand names.

2. Statements that are not implied claims

The agency has attempted to define as many groups of implied claims as possible so as to permit as many appropriate, nonmisleading implied nutrient content claims as possible in ***2369** this final rule. In addition, FDA examined the comments carefully to identify groups of label statements about ingredients and other attributes of foods that are not implied nutrient content claims. The agency finds that it can distinguish several types of statements that can be excluded from the requirements for nutrient content claims. The agency is describing these claims in new § 101.65(b).

a. Statements that facilitate avoidance

220. Several comments stated that some statements of the absence of a substance or an ingredient provide valuable information to consumers who seek to avoid certain substances. The comments noted that statements such as "100 percent milk free" or "contains no milk or milk fat" serve primarily to assist those buyers who adhere to Kosher dietary laws, or those who suffer from lactose intolerance, and wish to avoid dairy products. Other comments noted that statements such as "contains no MSG" or "contains no wheat flour" provide useful, indeed, sometimes vital, information to consumers who are sensitive to these substances. The comment stated that it was not clear from the proposal whether these ingredient statements would be permitted.

The agency has considered these comments and agrees that such statements are not nutrient content claims. Statements of the absence of an allergen are regulated under § 105.62 (21 CFR 105.62), which provides for labeling of foods for special dietary use by reason of the absence of an allergenic property. Statements that declare the absence of other food

components or ingredients that are not nutrients of the type required to be declared in nutrition labeling and that are intended to facilitate avoidance of the substance for such reasons as food intolerance, religious beliefs, or dietary practices (such as vegetarianism), e.g., "100 percent milk free," are also not nutrient content claims. FDA has included new § 101.65(b)(1) in its regulations to recognize this fact. However, the agency cautions that such a statement could be made in such a way as to connote a nutrient content claim. For example, a statement such as "contains no milkfat" made in context with other label information about the benefits of reducing fat intake, implies that the product is "fat free." In such a context, the statement would be a nutrient content claim subject to section 403(r)(1)(A) of the act. Also, for example, claims such as "no tropical oils" or "contains no animal fat" are usually made in a context that implies that the product has little or no saturated fat. Therefore, such claims would not be avoidance claims under the provisions of § 101.65(b)(1) but implied "saturated fat free" claims. Thus, they would have to meet the requirements for such claims.

b. Ingredients that do not serve nutritive purposes

221. Several comments stated that factual statements about ingredients, by their very nature, are not nutrient content claims and should be allowed on food labels (e.g., "no artificial colors" and "contains no preservatives"). One comment suggested that this criterion should also apply to nonnutritive or nutritionally insignificant sweeteners such as saccharin, aspartame, and acesulfame-K and to the brand name Nutra-Sweet. Such claims, the comment said, should be accompanied by "not a reduced calorie food" if appropriate, and the label should provide a statement referring specifically to the caloric and sugar declarations in nutrition labeling.

The agency continues to believe, as it stated in the proposal, that claims about the absence of certain substances that do not function as nutrients, such as preservatives and artificial colors, provide information important to certain consumers but are not nutrient content claims because they are not claims about the level of a nutrient. Consequently, such claims are subject to regulation under section 403(a) of the act, to ensure that they are truthful and not misleading, but not section 403(r). Accordingly, the agency is listing in new § 101.65(b)(2) as a second class of claims that are not nutrient content claims, those that are about substances that do not have a nutritive function and do not substitute for nutritive substances, e.g., "contains no preservatives" or "no artificial colors."

However, FDA does not agree with the comment's suggestion that this policy should also apply to label statements referring to the presence of nonnutritive or nutritionally insignificant sweeteners. In the past the agency has regulated statements like "artificially sweetened" and "sweetened with nonnutritive sweetener" as claims of special dietary usefulness (§ 105.66), which in some contexts imply that the food is "low calorie" or "reduced calorie." Elsewhere in this issue of the Federal Register, in a companion final rule on revisions to § 105.66 related to the nutrient content claims regulations in this final rule, FDA has discussed its policy on label statements that refer to the presence of a nutritionally insignificant sweetener in a food. In that document the agency reiterated its position that such claims are subject to either new § 105.66(a) and (b), or (e).

c. Ingredients that provide added value

222. A few comments stated that claims about ingredients that provide added value to products convey important information about the quality of the products and should not be considered implied nutrient content claims. The

comments suggested that claims such as "made with butter," "contains buttermilk," "made with whole wheat flour," "contains real fruit," or "made with natural, not processed, cheese" would be examples of added value claims.

The agency agrees that some of these claims would be useful as tools for the manufacturer to communicate to the consumer that the product is of high quality because premium or otherwise preferred ingredients have been used. In most instances, statements such as "made with butter," "made with whole fruit," or "contains honey" would not be considered to be a statement about the product's nutrient content. Accordingly, in new § 101.65(b)(3) the agency is listing claims about the presence of an ingredient that is perceived to add value to the product, such as "made with butter," "made with whole fruit," or "contains honey," as statements that are not nutrient content claims. However, there would be cases, such as "made with whole wheat flour," where the added value statement is made in such a context that it could imply not only that a preferred ingredient was used, but also that the product contained a certain level of a nutrient (e.g., fiber). Such statements would be subject to section 403(r) of the act.

d. Statements of identity

223. Some comments agreed with FDA's discussion in the proposal that factual statements that a particular ingredient constitutes 100 percent of the food (e.g., 100 percent corn oil or 100 percent Columbian coffee) are statements of identity and not implied nutrient content claims. In addition, one comment specifically requested that FDA clarify that the names of dietary supplements (e.g., Vitamin C supplements) will not be considered implied nutrient content claims.

The agency concludes that when an ingredient constitutes essentially 100 percent of the food, so that the name of the ingredient is the statement of identity, the name of the ingredient does not constitute an implied nutrient content claim. In such circumstances, the name of the ingredient constitutes ***2370** the common or usual name of the product as described in § 101.5 or the identity of the commodity as described in § 101.3. As such it must provide an adequate description of the food.

When the ingredient is not associated with a nutritional benefit (e.g., Colombian coffee), it is clear that the statement of identity does not imply that a nutrient is present or absent in a certain amount. When the ingredient is associated with a particular nutritional benefit (e.g., corn oil), declaring its presence could imply the presence or absence of a nutrient. However, when used as the statement of identity, the name of the ingredient does not imply that the nutrient is present in a certain amount. Rather, it describes the nature of the product and does not specifically characterize the level of the nutrient. Hence, it would not be considered a nutrient content claim. As for the comment that the names of dietary supplements (e.g., vitamin C supplements) are usually not nutrient content claims, FDA intends to deal with this issue in the rulemaking that it will conduct under the Dietary Supplement Act of 1992.

Accordingly, FDA is providing in new § 101.65(b)(4) that the name of an ingredient is not a nutrient content claim when the ingredient constitutes essentially 100 percent of a food, so that the name of the ingredient is the statement of identity of the food. The agency notes, however, that a statement of identity may include an express nutrient content claim (see e.g., the final rule on requirements for foods named by use of a nutrient content claim and a standardized term, published elsewhere in this issue of the Federal Register). Such nutrient content claims are fully subject to new § 101.13 and the regulations in part 101, subpart D.

224. Several comments suggested that common names or statements of identity of foods that include terms that relate directly or indirectly to the nutrient content of a food (e.g., "oat bran muffins") should be considered implied nutrient content claims. Other comments suggested that such statements are merely statements of the characterizing ingredient and should not be considered implied nutrient content claims. They suggested that "oat bran muffin" is not different from "carrot spice muffin." One comment stated that truthful statements such as these should be assumed to be nonmisleading unless there is evidence to the contrary and should be permitted as part of the statement of identity.

While FDA agrees that most statements of identity are statements about the character of a food, there are a limited number of statements of identity that contain the name of an ingredient that is associated with a nutrient or a nutritional benefit and that therefore may also be implied nutrient content claims, depending on what other statements are made on the label or in labeling. Examples of such statements of identity would be "corn oil margarine," "oat bran muffins," and "whole grain bread." The agency will evaluate such claims on a case-by-case basis in the context of the entire label and the labeling to determine whether they are nutrient content claims. For example, if the labeling of oat bran muffins includes a discussion of the importance of fiber in the diet, FDA believes that the "oat bran muffins" name is an implied claim that the muffins are high in fiber. If the labeling is devoid of such information, FDA is not likely to consider the name to be an implied nutrient content claim. Accordingly the agency is providing in new § 101.65(b)(5) that a statement of identity that names as a characterizing ingredient, an ingredient associated with a nutrient (e.g., "corn oil margarine," "oat bran muffins," or "whole wheat bagels") is not an implied nutrient content claim unless such claim is made in a context in which label or labeling statements, symbols, vignettes, or other forms of communication suggest that a nutrient is absent or present in a certain amount.

Statements of identity that are provided by a standard of identity subject to section 403(r)(5)(c) of the act are not subject to definition under section 403(r) of the act and are therefore not considered nutrient content claims.

e. Statements of special dietary usefulness

225. One comment requested that the agency clarify that FDA will not deem a statement of special dietary usefulness made on the label or in labeling of a food in accordance with part 105 of FDA's regulations to be an implied nutrient content claim solely because it represents the food to be for special dietary use.

The agency has considered this comment. As stated in the general principles proposal (56 FR 60421 at 60457), FDA views claims on a food relative to special dietary needs to be different from claims made on a food relative to the nutrient content of the food. The agency would not consider claims made solely to portray the usefulness of the food for supplying a particular dietary need that exists by reason of a physical, physiological, pathological, or other condition as described in part 105 to be a nutrient content claims subject to new § 101.13. A claim such as "use as part of a weight reduction program" in and of itself, would not be considered to be a nutrient content claim.

However, there are circumstances in which a claim that a food is useful in a special diet may be made in a context that portrays a nutritional aspect of the food relative to the general population. If, for example, in addition to including a claim that the food was part of a weight reduction program, the label said that the food was "low calorie," or the label contained other statements of specific nutritional information, then such statement would be subject to the require-

ments for nutrient content claims because the label contained information directed toward the general population. Accordingly, the agency is providing in new § 101.65(b)(6) that label statements made in compliance with part 105 solely to note that a food has special dietary usefulness relative to a physical, physiological, pathological, or other condition where the claim identifies the special diet of which the food is intended to be a part, is generally not a nutrient content claim.

3. Single nutrient implied claims

a. Ingredient statements

226. Many comments addressed how requirements for implied claims should be applied to ingredient statements like "contains oat bran" and "corn oil margarine." Some stated that ingredient statements should not be considered implied nutrient content claims. Other comments stated that even though there are good reasons for having ingredient statements on labels, the fact that a declaration is an ingredient statement does not preclude the possibility that it is also an implied claim. Some said that claims such as "contains no tropical oils" and "made with 100 percent vegetable oil" would be misleading to consumers who would be led to assume that such a product is low in or free from saturated fat, when that is often not the case. A few comments stated that to prevent ingredient claims from being misleading nutrient content claims, all ingredient statements should be subject to the provisions of section 403(r) of the act.

The agency disagrees both with the comments stating that no ingredient claims should be considered to be implied nutrient content claims, and with those that want all ingredient claims to be regulated under section 403(r) of the act. As discussed above, some ingredient statements clearly are not implied nutrient content claims, and ***2371** some clearly are, while other ingredient statements will have to be evaluated on a case-by-case basis to determine whether they are implied claims. The agency will evaluate ingredient statements in the context of the total label to determine whether they are implied claims and therefore subject to section 403(r)(1)(A) of the act. The agency's focus will be on whether the ingredient statement identifies a nutrient explicitly or by implication, and whether it states or implies that the nutrient is absent, or that it is present in a certain amount.

227. One comment disagreed with FDA's definition for single nutrient implied claims in proposed § 101.13(b)(2), stating that the phrase "leads a consumer to assume" should be changed to "consumers acting reasonably under the circumstances."This phrase is preferable, the comment said, because it requires that the label be interpreted reasonably, rather than in an arbitrary, unusual, or unreasonable fashion. The comment asserted that a standard that is based on the interpretations of a few credulous people is not legally sustainable. The comment stated that the phrase "consumers acting reasonably under the circumstances" correctly takes into account the context in which the statement is made.

The agency has considered the comment and disagrees that "consumers acting reasonably under the circumstances" is a more valid standard for implied nutrient content claims than the one proposed by the agency. The focus of FDA's definition of implied claims is on what the claim suggests. The definition is not intended to be a quantitative standard to determine the number of consumers who have a particular conception about an individual claim but is intended to focus on what the claim is saying. To clarify the intent of the definition, FDA is striking the phrase in question and replacing it with the word "suggests."

228. A few comments said that FDA should evaluate, on a case-by case basis, whether a manufacturer intends a particular label statement to make an implied nutrient content claim, and whether consumers perceive the statement to be that claim. The comments asserted that a similar approach has been supported by the courts in determining whether a product is sold as a food or a drug.

In making an evaluation of a label statement within the context of the labeling as a whole, FDA agrees that it should consider both the manufacturer's intent and consumer perception. However, it notes that intent means more than the manufacturer's subjective intent. See National Nutritional Foods Association v. Mathews, 557 F.2d 325, 334 (2d Cir. 1977). An article's intended use is established by its label, labeling, promotional materials, advertising, and "any other relevant source." Id.

FDA advises that it will evaluate ingredient label statements on a case-by-case basis using the definition of implied claims in new § 101.13(b)(2) and the other provisions of the regulations to determine whether a label statement is an implied nutrient content claim. As stated above, the agency's primary focus will be whether the statement identifies the nutrient explicitly or by implication, and whether it states or implies absence of that nutrient or its presence in a certain amount.

229. Several comments suggested that the agency should consult popular media, scientific articles, and consumer surveys to determine when an ingredient claim constitutes an implied nutrient content claim. Several of these comments suggested that implied claims should not be allowed on food labels unless there is scientific consensus as to what these terms mean. On the other hand, a few comments suggested that a statement about an ingredient is not an implied nutrient content claim, unless there is direct consumer survey evidence that a substantial number of consumers understand the statement to imply a specific nutrient claim. The comment contended that any other position would create chaos because manufacturers would continually be in doubt as to whether an ingredient claim would be interpreted by the agency to be an implied nutrient content claim.

Another comment asserted that claims must be interpreted in their historical context. The comment stated that "high in oat bran," implying "high in fiber," for example, is taken out of context. The comment stated that at the time the claim became widely used, consumers believed that they needed to eat oat bran, not soluble fiber, to lower cholesterol. The comment further stated that consumers wanted to know the amount of oat bran in a product in order to follow a diet high in oat bran. However, current scientific evidence may not substantiate this early finding, and the necessity for consuming large amounts of oat bran may not currently be supported by scientific data. Therefore, for an implied claim to be considered valid, the comments said, current scientific data must be considered.

The agency agrees that nutrient content claims should be defined so as to be meaningful to consumers. It has attempted to ensure through the definitions established in these regulations that permitted claims will assist consumers in maintaining healthy dietary practices. In addition, where possible, FDA has used information on consumer understanding of terms. However, the agency is not persuaded that direct consumer survey information is always needed for it to provide clear guidance to manufacturers on whether an ingredient statement is an implied nutrient content claim. As discussed above, FDA is describing in this document some label statements that clearly are nutrient content claims, and others that clearly are not. For those label statements not addressed in this document, manufacturers who wish guidance can submit a petition requesting approval of a claim. The minimum requirements for information needed to

support such a request are described in new § 101.69. Petitioners are welcome to provide consumer survey information as well as other types of information in support of a petition.

230. Some comments asserted that FDA's definition of implied nutrient content claims should be limited to those statements that either expressly or by implication describe the level of a nutrient present in a food, as opposed to simply describing the food's composition. One comment stated that such an approach is consistent with Congressional intent as recorded in the House Report, which states:

An example of an implied claim covered by this section would be the statement "lite", which implies that the product is low in some nutrient (typically calories or fat), but does not say so expressly, or "high oat bran" which conveys an implied high fiber message.

(H. Rept. 101-538, 101st Cong. 2d sess. (June 13, 1990).)

Another comment asserted that it would be inconsistent with the language of the 1990 amendments to regulate claims about an ingredient that do not characterize the level of that ingredient as implied nutrient content claims. The comment requested that FDA specifically exempt ingredient claims that do not directly or indirectly refer to the level of a nutrient (e.g., "contains oat bran" and "made with vegetable oil").

As already discussed, FDA agrees that statements that describe (expressly or by implication) the level of a nutrient present in a food are nutrient content claims. In addition, for ingredients with nutrient implications (e.g., "bran" implies fiber and "tropical oils" implies saturated fat), a claim that describes the ***2372** level as "high," "low," or "free" clearly constitutes a nutrient content claim.

The agency does not agree, however, that claims such as "made with oat bran" and "contains vegetable oil" should be exempt from the regulations. It is not clear to FDA that such claims describe the nature of the food and not the level of a nutrient. The agency notes that it is providing in new § 101.54 that a claim that a food is a "good source" of a nutrient can only be made if the nutrient is present at 10 percent or more of the RDI or the DRV per serving of the food. The agency is also providing for use of the terms "contains" and "provides" as synonyms for "good source." As a result, "contains fiber" is a defined expressed claim that must meet the 10 percent of the DRV criterion.

The question then becomes whether "contains oat bran" and "contains whole wheat" imply that the food is a "good source of fiber." Some comments state that such claims are implied nutrient content claims, while others argue that they are statements about an ingredient and not the level of a nutrient. The agency concludes that, in certain contexts, these statements would be nutrient content claims because they call attention to the fact that the product has been made with an ingredient that contains a valuable nutrient. For example, if a label declared "Joe's Oat Bran Muffins" or "Joe's Muffins, made with oat bran" the prominence of "oat bran" may not call attention to it is a way that proclaims its nutritional value. However, if "Joe's Muffins" bore a bright banner with "oat bran" in large, bright letters, the emphasis on "oat bran" would likely place it in the overall context of a nutrient content claim. However, FDA will evaluate these claims on a case-by-case basis, taking into account the entire label and the labeling, including the placement and prominence of the claim as well as the text of label statements.

231. Some comments asserted that FDA should narrow the definition of nutrient content claims to include only those claims specifically mentioning a nutrient of the type addressed in section 403(q) of the act and of the type appearing as part of the nutrition panel (e.g., fat or cholesterol). Similar comments asserted that any statement regarding an ingredient, as opposed to a nutrient, should not be considered an implied claim. One comment asserted that even those ingredient claims that imply that a nutrient is absent or present in a certain amount are not implied claims. Rather, according to these comments they are more appropriately considered statements of identity or parts of ingredient claims. Some comments specifically disagreed with the House report and FDA that the phrase "high in oat bran" should automatically constitute an implied fiber claim. These comments argued that this claim, as well as others that simply describe the ingredients present in a product in a truthful and nonmisleading manner, should be considered ingredient statements. One comment supported this position by stating that these claims do not automatically lead a consumer to assume that fiber is absent or present in any amount. The comment asserted that such a statement simply advises consumers that oat bran is used as a significant ingredient in the product. The comment went on to say that while oat bran does have some relationship to fiber, consumers will not automatically associate the two. A similar comment requested that FDA alter proposed § 101.13(b)(2) to read, "e.g., high in oat bran, which may imply that a food is also high in fiber."

The agency does not agree that nutrient content claims under section 403(r)(1)(A) of the act are limited to label statements that specifically identify a nutrient, e.g., fat or cholesterol. The legislative history identifies the term "high in oat bran" as an example of an implied nutrient content claim (H. Rept 101-538, 101st Cong. 2d sess. 19 (June 13, 1990)). This statement provides strong evidence that when Congress said that "a claim * * * which expressly or by implication—characterizes the level of a nutrient * * * must be made in accordance with section 403(r)(2)," it intended to include ingredient claims that imply that a nutrient is present at a particular level in, or is absent from, the food. Accordingly, FDA rejects the comment that objected to this interpretation.

The agency advises that there are long established relationships between ingredients and nutrients that are covered under the definition of implied nutrient content claims. Some of these ingredient-nutrient relationships have been regulated as claims for special dietary use. For example, terms like "sugar free" have been regulated by FDA as implying that the product is low or significantly reduced in calories (§ 105.66). In addition, FDA has issued warning letters regarding foods that contain tropical oils (which contain significant levels of saturated fat) when they bear label statements, like "100 percent vegetable oil," that imply that these ingredients have low levels of saturated fat.

Consequently, FDA is not granting the request to exempt from the nutrient content claim requirements ingredient claims that do not explicitly identify a nutrient. However, as discussed in the previous comment, the agency acknowledges that some statements that name ingredients that have nutritional relevance are not nutrient content claims. The agency will evaluate such claims on a case-by-case basis. In addition, where appropriate, manufacturers may submit petitions under new § 101.69 requesting approval of specific claims.

232. A few comments suggested that only those ingredient statements that meet the definition for a defined nutrient content claim should be considered implied nutrient content claims, and that all other ingredient claims should not be considered nutrient content claims. However, several other comments suggested that all ingredient claims that imply that a nutrient is either absent or present at a particular level, whether or not they met the definition of the expressed term, should be considered implied nutrient content claims.

Some of the latter comments said that only those implied claims that meet the requirement for an analogous expressed claim should be permitted on the label or in labeling. For example, several comments said that a statement that a product "contains oat bran" implies that the product is a good source of fiber and should, therefore, only be permitted on foods that meet the definition for "good source of fiber." The comments said that requiring that the expressed claim be met in order to make an implied claim would be effective in preventing manufacturers from using claims on food that may not meet appropriate nutritional standards. Another group of comments stated that any "no (ingredient)" claims (e.g., "contains no tropical oils") that imply that the product is free of a nutrient, but that disparage the absent ingredient, could be misleading if there is inadequate scientific support for health concerns about the ingredient and therefore should be prohibited. The comments presented various other examples to either support or oppose a requirement that an implied ingredient claim that meets the requirements for an explicit nutrient content claim should be permitted.

The agency agrees that ingredient claims that make implied representations about the level of a nutrient in a food, whether or not they meet the definition of the expressed claim, should be considered implied nutrient content claims. This conclusion is consistent with section 403(r)(1)(A) of the act, which states that a food can be misbranded by a statement that ***2373** expressly or by implication characterizes the level of a nutrient in a food. An ingredient claim that implies that a nutrient is present in the food at a particular level, but that fails to meet the requirements for the equivalent express claim, will misbrand the food under section 403(r)(1)(A) of the act.

The question of whether claims like "contains no tropical oil" should be prohibited as misleading because they disparage the ingredient will turn on what the scientific evidence shows about the ingredient. If it is commonly known that the ingredient for which absence is claimed is a source of a nutrient for which the current dietary guidelines recommend decreased or moderated intake, then there is no reason for the agency to refuse to permit the claim. The fact that FDA would permit such a claim, however, would in no way represent a disparagement of the ingredient. The claim provides a means by which a manufacturer could highlight the saturated fat content of its food. It does not imply that the ingredient in question is a "bad" food.

233. One comment suggested that FDA allow companies to use expressed or implied nutrient content claims (in brand names or otherwise) that have not been defined or specifically approved by the agency if the claim is not false and misleading and is consistent with, and explained by, an immediately adjacent term that is defined in the agency's regulations. Alternatively, the comment requested that FDA permit ingredient claims that did not meet the expressed nutrient content claims definition but require them to be followed by a factual statement clarifying the nutrient content implication (e.g., "no tropical oils—this product contains 2 g of saturated fat" or "contains oat bran—not a significant source of fiber"). The comment stated that, in effect, companies would be allowed to define certain ingredient claims as implied nutrient content claims. Such a process would be in addition to the petition process established by FDA, thus allowing a company to choose whether to determine its own definition of an expressed or implied nutrient content claim or to petition the agency for a codified definition. The inclusion of a self-definition procedure would, the comment contended, be more in keeping with Executive Order 12630. Also, according to the comment, under such a policy, companies would not be forced to abandon nonmisleading implied claims and brand names, as they would under FDA's proposed rule. Companies would also not be made to change labels repeatedly, once by the effective date of the regulations and again after each new implied nutrient content claim is approved. Finally, the comment stated

that the rule proposed by FDA would lead to a proliferation of unexplained terms that have been defined by FDA in the regulations but which have little or no meaning to consumers, whereas the procedure suggested in the comment would require the use of a defined term on the label to explain the intended meaning of the implied claim, adding significantly to consumer understanding. The comment asserted that the alternative method is fully consistent with the language and the intent of the 1990 amendments.

The agency does not agree that allowing manufacturers to use undefined claims that do not meet the definition for an expressed claim to be accompanied by a defining statement is consistent with either the intent or the letter of the 1990 amendments. The act provides that claims that characterize the level of a nutrient either expressly or by implication "may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary" (section 403(r)(2)(A)(i) of the act). Thus, Executive Order 12630 is not relevant to the approach that FDA is required by statute to take on this matter. To do as the comment requests and allow manufacturers to continue using any label statements they choose (provided they add a defining statement as explanation) would be inconsistent with the letter and spirit of the act. The agency points out that under section 403(r)(4)(A) of the act, any person may petition the agency for permission to use terms that are subject to section 403(r)(2)(A)(i). This section also provides timeframes in which the agency must act on these petitions. Thus, there should not be any undue delay in obtaining a determination as to whether the claims can be used. Because the act specifically provides a mechanism by which use of claims can be authorized, the agency concludes that it would be inappropriate for FDA to establish an alternate mechanism by which such claims can be used.

The agency disagrees that companies would be required to make frequent label changes because of the approval of each new term. The company could decide what term it wants to use, determine whether the use of the term has been authorized, and if it has not been, petition for such authorization. Once the use of a term is authorized, the firm would be free to use it. Any change in the company's labeling made after that point because FDA approved a new term would occur because the company wanted to take advantage of the term, not because FDA compelled a change.

The agency also disagrees that there would be a proliferation of unexplained terms defined by FDA that would have little meaning to consumers. The agency is establishing only a distinct group of terms and synonyms with well defined meanings that may be used as nutrient content claims. Any additional terms that are included in response to a request of a petitioner will have been shown to be as well supported as those terms originally defined.

The agency concludes that the approach to regulating implied nutrient content claims suggested by the comment is not consistent with the structure established by 1990 amendments and will not promote better consumer understanding of label claims. Accordingly, FDA is not permitting use of undefined nutrient content claims accompanied by an explanation.

234. Many comments asserted that factual declarations of the amount of an ingredient (e.g., "160 mg of sodium," or "contains less than 300 calories") do not constitute implied nutrient content claims. Other comments maintained that statements concerning the percent of a nutrient (e.g., "9 percent fat") should also not be considered implied nutrient content claim.

The agency advises that declarations of the amount of a nutrient or the percent of a nutrient are provided for in new §

101.13(i). That provision, pursuant to section 3(b)(1)(A)(iv) of the 1990 amendments, states that such statements must meet the definition for a defined term or must be accompanied by a statement that the food does not meet the appropriate definition. Comments 16 through 19 of this document contain a full discussion of such claims.

235. One comment suggested that "equivalent" be defined as a nutrient content claim so that comparisons could be made to indicate that a food had the amount of a nutrient equivalent to a reference food, e.g., "contains as much fiber as an apple."The comment stated that this type of claim was particularly appropriate for dietary supplements.

The agency advises that it considers the example given in the comment to be an implied claim about the fiber content of the food. "Contains as much dietary fiber as an apple" implies that one apple is a good source of fiber, and that by being equivalent in fiber to an apple, the labeled food is also a good source of fiber. Such a claim can be used to provide valid, valuable information to the consumer about the nature of a ***2374** product in terms of another product that the consumer already understands. However, the agency believes that such a statement would be misleading if the labeled food was compared to the level of nutrient in a food that was not consistent with dietary guidelines, namely the amount of nutrient in a food which is "free," " low," a "good source," or "high." Likewise such a claim would be misleading if comparisons between the foods were not made on a common basis. Because a serving of the product is the amount customarily consumed in one eating occasion (a value which is applicable to all foods), the agency concludes that comparisons using this type of claim should be made on a per serving basis.

Accordingly, the agency is providing in new § 101.65(c)(2) for the use of equivalence claims using the phrases "contains the same amount of (nutrient) as a (food)" and "as much (nutrient) as a (food)" to imply that the reference food is a good source of specified nutrient, and that on a per serving basis, the labeled food is an equivalent, good source of that nutrient (e.g., "as much fiber as an apple,""contains the same amount of Vitamin C as a glass of orange juice").

236. Several comments requested that the agency define specific implied claims so that their use would be permitted in labeling. Claims that were suggested included "high in oat bran," "contains no oil," "no tropical oils," and "contains canola oil." While the comments suggested definitions for the claims, they were not always in agreement on what the definitions should be.

The agency has carefully considered these terms and is providing its interpretation of the nutrient content implied by the label statement. Label statements about oils like corn, sunflower, safflower, and canola generally refer to the oils' fatty acid content. Accordingly, FDA considers a statement about a type of oil as an ingredient, such as "made with canola oil" or "contains corn oil," to generally imply that the oil in the product was low in saturated fatty acids. The statement "made only with vegetable oil" implies that because vegetable oil was used instead of animal fat, the oil component was low in saturated fat.

A claim that a product contains "no tropical oils," including a statement about the absence of a specific tropical oil, assumes that the consumer understands that tropical oils have a large amount of saturated fats. Such a claim would imply that another oil had been used that did not have a large amount of saturated fat. Consequently, a claim that a product "contains no tropical oils" would imply that the product is "low in saturated fat."

The agency considers that a statement that a product "contains no oil" implies that the product is not made with lipids (fat). Accordingly, such a claim would imply that the product was "fat free." Such a claim on a product that contained another source of lipids (e.g., animal fat) would be misleading.

Further, the agency considers that a claim that a product is made with or otherwise contains a whole grain, a bran, or any type of dietary fiber (such as soluble fiber), implies that the product is a good source of total dietary fiber. Such a claim would therefore be misleading if the product did not contain sufficient fiber derived largely from the sources of fiber mentioned such that the product met the definition for "good source of dietary fiber." However, a claim naming these ingredients that also used the term "high" or a synonym thereof would be misleading if the product was not "high in dietary fiber."

The agency would generally not consider ingredient claims that are consistent with the meanings that it has outlined above to be misleading under section 403(a) of the act. However, as with any implied claim, the agency will consider the appropriateness of the use of the claim in the context in which it is made.

The agency advises that it does not consider that the terms that it has mentioned provide an all-inclusive list of those ingredients that imply the level of a nutrient. Claims for other nutrients will be considered on a case-by-case basis.

In conclusion, a claim that states or implies a characteristic that distinguishes a particular nutritional attribute of an ingredient will generally be considered an implied nutrient content claim. Whether or not it is a nutrient content claim will depend on the context in which it is presented, taking the entire label into consideration. The level of the ingredient may be implicit or explicit. The agency has described generically in new § 101.65(c)(3) circumstances under which such implied claims can be made. The regulation states that claims may be made that a food contains or is made with an ingredient that is known to contain a particular nutrient, or is prepared in a way that affects the content of a particular nutrient in the food, if the finished food is either low in or a good source of the nutrient that is associated with the ingredient or type of preparation. If a more specific level is claimed (e.g., "high in ————"), that level of the nutrient must be present in the food. For example, a claim that a food contains oat bran is a claim that it is a good source of fiber; that a food is made only with vegetable oil is a claim that it is low in saturated fat; and that a food contains no oil is a claim that it is fat free.

The agency believes that the approach that it is taking in § 101.65(c)(3) strikes an appropriate balance between the interest of industry in making claims and the consumers' interest that claims that appear on the label accurately and fairly characterize the level in the food of the nutrient that, either explicitly or implicitly, is the subject of the claim.

b. Accompanying information

237. One comment suggested that implied nutrient content claims should be accompanied by appropriate referral statements that are consistent with the requirement for such statements to accompany nutrient content claims.

The agency advises that implied nutrient content claims that are defined in new § 101.65 (a)(2), must comply with all of the requirements for nutrient content claims described in new § 101.13. Among the requirements is the requirement for referral statements. In addition, FDA advises that as with other nutrient content claims, labels bearing such implied

claims must also bear nutrition labeling in accordance with the requirements of new § 101.9 or, where applicable, new § 101.10. For clarity, the agency is listing the latter requirement in new § 101.65(a)(3).

4. General nutrition claims

In the general principles proposal (56 FR 60421 at 60423) FDA proposed to include in § 101.13(b)(2) a provision that label statements that imply that a product would be useful to consumers in selecting foods that are helpful in achieving a total diet that conforms to current dietary recommendations (e.g., "healthy") are implied nutrient content claims.

a. General comments

238. Many comments asserted that FDA's definition of implied nutrient content claims should not include claims that imply that a "food because of its nutrient content may be useful in achieving a total diet that conforms to current dietary recommendations (e.g., healthy)."Some of these comments stated that Congress showed no interest in regulating such claims but instead was concerned only with regulating those statements that characterize the level of a nutrient present in a food. One such comment noted that neither the act nor the legislative history contains any ***2375** language addressing general nutrition claims.

The agency does not agree with these comments. First, the reading of section 403(r)(1)(A) of the act suggested by these comments is clearly too narrow. A claim that a food, because of its nutrient content, may by useful in maintaining healthy dietary practices is clearly a claim that characterizes the level of nutrient in that food. The claim is essentially saying that the level of nutrients in the food is such that the food will contribute to good health.

Moreover, Congress was clearly concerned with such claims. The October 24, 1990, proceedings in the Senate show that one purpose of the 1990 amendments was to regulate the use of nutrient content claims that appear on food labels and labeling in order to help consumers make appropriate dietary choices (136 Congressional Record S16610 (October 24, 1990)). In addition, section 403(r) of the act itself, repeatedly uses the phrase "* * * will assist consumers in maintaining healthy dietary practices" to describe the information for which provision is being made (see e.g., section 403(r)(2)(A)(ii)(II) and (r)(2)(A)(iii)(I) of the act).

The agency is therefore not persuaded that this aspect of the proposed definition of implied nutrient content claims is inconsistent with the language of the act, the intent of Congress, or the goals of the 1990 amendments. However, FDA is modifying § 101.12(b)(2)(ii) to replace the phrase "* * * achieving a total diet that conforms to current dietary recommendations" with the statutory phrase "* * * maintaining healthy dietary practices."

239. Some comments objected to regulating terms such as "nutritious," "healthy," and "wholesome" under section 403(r) of the act because they have different meanings depending on their contextual use and would be difficult to define. These comments asserted that the agency should instead regulate the use of such terms on a case-by-case basis under section 403(a) of the act. The comments asked for assurance that these terms would not be regulated under section 403(r) of the act.

To ensure that consumers have accurate and adequate resource materials and information, the agencies have begun, and will continue to: (1) Conduct and report on existing and planned food labeling research; (2) develop education initiatives at the national and local levels; (3) hold regularly-scheduled meetings to build labeling education exchanges; (4) produce video news releases and longer videos; and (5) produce an array of public education materials, including a special edition of FDA Consumer magazine that summarizes the final food labeling regulations, and brochures (in English and other languages) on the new label and how to use it to meet the Dietary Guidelines for Americans. These materials will be targeted to the general public, nutritionists, such special groups as ethnic minorities, and others. Organizations will also be able to use these resource materials to develop educational materials of their own.

318. Several comments stated that the proposed rules define claims so narrowly and require such burdensome disclosure requirements that manufacturers would have little or no incentive to develop new nutritionally improved products to qualify for nutrient content claims, to make substantial investments in research and development, or to develop the supporting manufacturing marketing capabilities.

The agency agrees that new products that are truly nutritionally improved can make positive contributions to public health. Thus, FDA is sensitive to the concerns raised by the comments that the proposed definitions could inhibit innovation. In response, FDA has attempted in the final regulations to make the definitions more flexible, while at the same time ensuring that the terms will be useful in maintaining healthy dietary practices and will be used in a manner that is truthful and not misleading. FDA believes that the final regulations, as revised, will stimulate innovation in food product research and the development of new versions of foods and food formulations that will meet the definitions, because nutrient content claims are an important aspect of a product's marketability.

319. Several industry comments stated that because these regulations depart significantly from the European Community (EC) nutrition labeling directive and from the Food Agricultural Organization/World Health Organization (FAO/WHO) Codex International recommendations, they will impede the resolution of differences under the General Agreement on Tariff and Trade.

The agency recognizes that the 1990 amendments and substantive provisions of these regulations are not in complete accord with the FAO/WHO Codex food labeling regulations or with regulations or directives of the EC or other countries. The agency also recognizes that this is an area that the FAO/WHO Codex has not yet addressed. Therefore, the regulations may have an impact on the resolution of issues related to international trade. However, these regulations are fully responsive to the 1990 amendments. The agency believes that these regulations will provide U.S. consumers with accurate and reliable information, information that consumers in other countries could use and may demand of their food regulators. The agency believes that the principles of these regulations may be adopted by other countries and serve as a basis for harmonization. This agency is committed to working with representatives of other nations and international organizations to achieve the greatest degree of harmonization possible.

VIII. Terms that Describe Other Aspects of Food

A. "Fresh" and Related Terms

The 1990 amendments do not require that FDA define labeling terms such as "fresh" that do not make nutrient content claims. However, the continued misuse of "fresh" and related terms in the marketplace, and the consumer confusion that has resulted, led the agency to propose definitions in the general principles proposal that establish labeling regulations to govern the use of "fresh," "freshly——" (e.g., "freshly baked"), and "fresh frozen" as they appear on the label or in the labeling of foods, including the use of these terms in brand names and as sensory modifiers (fresh tasting) (56 FR 60421 at 60462).

FDA also identified several questions in the general principles proposal regarding the use of the term "fresh" and solicited comments on whether these should be addressed in the final rule. The agency asked whether: (1) It ***2402** should allow the use of the term "fresh" to describe certain raw foods that have been treated with ionizing radiation in accordance with § 179.26 (21 CFR 179.26), specifically, those foods where irradiation at a maximum dose of 1 kiloGray (100 kilorads) is permitted; (2) it is appropriate to limit use of the term "freshly —— " to foods that are available for sale within 24 hours of preparation as the agency proposed, or whether other approaches to defining this term should be considered and incorporated into the final rule; (3) it would be misleading to allow the use of the term "freshly prepared" to describe recently prepared foods that contain processed ingredients; (4) it is important to the consumer to be able to distinguish between processed products made with fresh, as opposed to processed ingredients, and whether FDA should permit the use of a factual statement such as "spaghetti sauce—made with fresh mushrooms" on processed foods made from fresh as opposed to processed fruits and vegetables. Related to this issue, FDA requested comments on whether the inclusion of blanching as part of a continuous process at a facility should preclude labeling the ingredient as fresh; (5) the use of remanufactured ingredients affects the attributes of a finished product, such as a tomato product, to such a degree that the consumer is misled about the product if its labeling does not specifically declare the remanufactured nature of the ingredient. The agency asked whether it should require the use of a term such as "reconstituted," "remanufactured," or "made from concentrate" on the PDP of processed products made from remanufactured ingredients; and (6) extended shelf life foods merit the use of the term " freshly prepared," and if so, what factors should be considered to ensure that the term is not used in a misleading manner.

320. Several comments objected to the agency issuing a regulation that would define "fresh" and related terms while it is implementing the mandatory requirements of the 1990 amendments. These comments argued that a regulation governing the use of the term "fresh" is not mandated by the 1990 amendments and does not meet the President's reform directive of January 28, 1992. Some of these comments urged FDA to defer rulemaking on use of the term "fresh" until after it completes the mandatory rulemaking required by the 1990 amendments.

The agency does not agree that it should defer rulemaking to define "fresh." Although the 1990 amendments do not require the agency to define the term "fresh," FDA believes that a definition for certain uses of the term "fresh" is necessary because the term has been continuously misused in certain contexts. FDA concludes that a regulatory definition will discourage such misuse and will allow the agency to efficiently enforce the misbranding provisions of the act, particularly section 403(a) of the act, when the term is misused.

In issuing regulations concerning use of the term "fresh," the agency has also taken into account the requirements outlined in the President's reform directive regarding burdensome government regulations. Having concluded that it is necessary to promulgate regulations concerning use of the term "fresh," the agency considers that taking such action at this time is the most cost effective option because any required labeling changes that result from this action can be

accomplished simultaneously with the label changes required by the 1990 amendments.

321. Comments addressing the proposed definition for the term "fresh" expressed widely diverse views on this subject. The agency received comments that supported the proposed definition, suggested alternatives to it, opposed the provision as proposed, or opposed FDA defining the term altogether.

Comments suggested that "fresh" should be defined as recently made, produced, or harvested foods that are not stale, spoiled, or withered. Numerous comments suggested that in addition to defining "fresh" as meaning raw and unprocessed, the term can also be associated with product quality, and therefore, a case-by-case determination may have to be made to determine where misleading uses of "fresh" have occurred rather than establishing one definition for the term. Some other comments contended that "fresh" has various meanings, and that the context in which it is used should ultimately dictate its meaning. One comment argued that the term "fresh" should be defined in such a way to distinguish between "garden fresh" and "market fresh."

Some comments that favored a regulation to govern the use of "fresh" suggested that the term should not refer to products prepared from concentrates, to commercially packed pasteurized products, or to products that are stored in cold storage warehouses until they are marketed. Some of these comments also stated that raw produce that has been trimmed or cut into smaller pieces should not be precluded from being described as fresh.

Some comments suggested that the proposed definition was too restrictive and did not consider the many ways consumers use and understand "fresh" because, as defined in the proposal, the term could only be used to describe raw, unprocessed foods. For example, these comments pointed out that, as proposed, the term "fresh" could not be used to describe some foods that are generally accepted by consumers as "fresh," such as fresh bread and pasteurized milk.

Some comments argued that there are numerous consumer perceptions associated with the term, and therefore, it is impossible to derive one definition that is universally acceptable. Another comment suggested that FDA should not permit the use of the term "fresh" on food labels because it is too difficult to define the term in a manner that would encompass all of the ways consumers use and understand it.

The volume of comments that expressed significantly different conceptions about the term "fresh," and that expressed reservations about the proposed definition of "fresh," has led FDA to reconsider this provision. FDA has been persuaded that the proposal was too restrictive, because it did not allow for various contexts in which "fresh" is appropriately used and would have disallowed uses of this term that are not misleading and are widely accepted by consumers ("fresh bread"). After considering all of the comments, FDA concludes that it is not necessary to establish a definition for "fresh" that would address all uses of this term as the proposal would have done.

However, FDA concludes that a definition for "fresh" is necessary to preclude the types of misuses of the term that the agency most frequently encounters, i.e., use of the term to imply that a product is unprocessed, when in fact it has been processed. The definition has particular applicability where there are processed and unprocessed forms of the food available. The use of the term "fresh" would imply that the food is the unprocessed form. If this is not the case, the food is misbranded. Therefore, FDA has revised the definition of "fresh" in § 101.95(a) so that it retains the same criteria that were in the proposal, but it only applies the criteria when the term "fresh" is used in a manner that suggests

or implies that the food is unprocessed.

FDA is providing some examples of how certain foods relate to the definition of "fresh." These examples are intended to be illustrative. Except in a few cases where FDA believes clarification is necessary, FDA is not providing specific guidance in this final ***2403** rule on the many types of foods for which comments stated an opinion concerning the appropriateness of the use of the descriptive term "fresh." Under the definition of "fresh" that the agency is establishing, foods such as cut raw vegetables and expressed juices from raw produce could bear the term "fresh" on the label because these foods meet the requirements of the definition. However, if the term "fresh" were used to describe a pasteurized orange juice, that term would misbrand the product because when used in this context, the term implies that the food is unprocessed (e.g., fresh squeezed orange juice), when in fact it is a pasteurized food.

By contrast, in the case of pasteurized milk that is labeled as "fresh," such a food would not be subject to new § 101.95(a) because this term does not imply that milk is unprocessed inasmuch as consumers recognize that milk is nearly always pasteurized, and that unpasteurized milk (in states where it is permitted to be sold) would be labeled as "raw" milk. Also, the term "fresh" as used on bread would not be subject to new § 101.95(a) because bread is not a food that exists in a raw state, and the term "fresh bread" does not imply that the food is unprocessed and in its raw state. For clarity, FDA is including milk in § 101.95 as an example of a use of the term "fresh" that is not subject to this regulation, and pasta sauce as an example of a food that is subject to this regulation.

The agency advises that uses of the term "fresh" to describe foods that do not suggest or imply that a food is unprocessed will not be subject to the definition established for "fresh." However, all uses of this term in food labeling are subject to the requirements of 403(a) of the act, the act's prohibition of false or misleading labeling. Therefore, the agency has the authority to take action on a case-by-case basis against foods that use the term "fresh" on the label in a manner that is false or misleading, even though the food may not be subject to new § 101.95(a).

322. One comment stated that the agency should adopt FSIS' policy memo 022C that outlines conditions in which the term "fresh" can be used on approved labeling of meat and poultry products. FSIS' policy memo 022C states that the term "fresh" may not be used as part of a name on any product that is canned, cured, dried, chemically preserved, or hermetically sealed. In addition, FSIS' policy memo 022C states that "fresh" may not be used on any poultry or poultry part that has been frozen or previously frozen at or below zero degrees Fahrenheit.

FDA does not find it appropriate to adopt FSIS' policy memo O22C that addresses use of the term "fresh" on the labeling of meat and poultry products. Although the memo has provided FDA with useful information in formulating its "fresh" policy, the reference of the policy memo is limited in that it specifically addresses meat and poultry products and the conditions under which they are sold. Therefore, the agency does not find merit in the suggestion that it adopt the provisions set forth in that policy memo.

323. Several comments addressed the use of "fresh" as it relates to crabmeat. Comments on this issue urged FDA to reconsider its definition for "fresh" because as proposed, it would prohibit the use of this descriptor to describe crabmeat. These comments argued that it is not feasible for consumers to purchase raw crabmeat, and, furthermore, use of the term "fresh" has been traditionally associated with crabmeat that has been cooked and picked but not subjected to any other processing procedures. Other comments stated that some consumers look for the term "fresh

crabmeat" as a way of distinguishing it from pasteurized crabmeat that is a lower price and that requires special handling.

FDA finds that the terms "fresh" or "fresh picked" as used to distinguish picked crabmeat from pasteurized crabmeat is not a use of the term "fresh" that implies that the food is unprocessed (as it is understood to mean that the food has been cooked and is not raw), nor is it misleading to consumers who are accustomed to this usage. Therefore, such use of the term is not subject to new § 101.95(a), and FDA will not object to such usage of the term.

324. One comment disagreed with some of the proposed exemptions that allowed for use of the term "fresh," i.e., (1) If an approved wax or coating has been applied to raw produce, (2) if a mild chlorine or mild acid wash has been applied to raw produce, or (3) if raw produce has been treated with approved pesticides after harvest. The comment stated that it is misleading to use the term "fresh" to describe raw produce that has been washed with a chlorine or mild acid wash, waxed, or treated with an approved pesticide. However, another comment suggested that the agency should permit use of the term "fresh" on foods whose surface is treated with ascorbic acid, calcium chloride, citric acid, potassium chloride, or sodium bisulfite, provided that these treatments are used at levels allowed by FDA regulations. The comment argued that these treatments affect a food's surface, and that they do not appreciably affect the body or alter the state of the food.

The agency does not agree that surface treatments such as waxing, washing with a mild chlorine or a mild acid wash, or the use of an approved pesticide should preclude describing the food as "fresh." As stated in the proposal, these applications are recognized as routine practices in the distribution and handling of raw produce. However, the agency does not agree that the use of the term "fresh" is appropriate if a food has been subjected to chemical treatments, including but not limited to antioxidants, antimicrobial agents, or preservatives, that introduce chemically active substances that remain in or on the food to preserve or otherwise affect the food. Thus, FDA is not providing for the use of the term "fresh" on foods that have been treated with the substances listed in the second comment. FDA is, however, retaining the exempting provisions in the final rule and is redesignating them as § 101.95(c)(1).

325. A number of the comments stated that use of low dose ionizing radiation has little effect on the attributes of a food in its raw state, and that "fresh" labeling should be permitted for foods that have been treated with low dose ionizing radiation. Other comments that supported the use of the term "fresh" on some irradiated foods suggested that irradiation enables a product to remain wholesome.

A small number of comments argued that use of the term "fresh" to describe certain irradiated raw foods would be misleading because irradiation is considered to be a form of processing that results in a loss of vitamins in foods. The comments also stated that safety procedures have not been established for irradiated foods, and that irradiation may affect the food in some unhealthful way. None of the comments that opposed the use of ionizing radiation on raw unprocessed foods provided the agency with supporting data to substantiate these claims. A few comments suggested that the labeling information associated with irradiated foods should state whether the food has been exposed to gamma or ionizing radiation from man-made sources. The majority of the comments agreed that the agency should require comprehensive and informative labeling on any raw unprocessed food that has been irradiated.

After reviewing the comments pertaining to the use of "fresh" to describe foods that have been exposed to ionizing

radiation, the agency notes ***2404** that the concerns expressed relate primarily to safety and to the use of appropriate labeling to identify foods that have been irradiated. These comments appear to confuse safety and proper identification of foods that have been irradiated with perceptions related to the state of freshness of these foods. None of the comments, however, provided information to support the contention that use of currently approved low doses of irradiation on raw foods (not exceeding 1 kiloGray (100 kilorads)) would degrade the characteristics of a food associated with a food's raw state.

Under the provisions of § 179.26(b), irradiation of fresh foods is limited to the use of low dose irradiation (not to exceed 1 kiloGray) for the purpose of disinfestation of arthropod pests in food, for growth and maturation inhibition of some fresh foods, and for control of Trichina spiralis in pork carcasses. In approving these uses of irradiation, the agency concluded that foods treated with the approved levels of ionizing irradiation are safe. FDA requires that retail packages and bulk containers of such food bear a unique logo that distinguishes irradiated from nonirradiated foods and the statement "treated with radiation" or "treated by irradiation" (§ 179.26(c)). Therefore, FDA concludes that the safety and proper identification of any food that has been treated with low dose ionizing irradiation is not relevant in determining whether food that is "fresh" under § 101.95 before irradiation can continue to be described as "fresh" after such treatment.

The test for determining the appropriateness of applying the term "fresh" to foods treated with post harvest applications, including treatment with low dose irradiation, is the effect that the process has on a food. The low doses of irradiation approved for fresh foods (less than 1 kiloGray) are used to prevent maturation (sprouting) and to kill insects (§ 179.26(b)). Exposure of raw food to low dose irradiation typically causes insignificant changes in their appearance and nutrient content. While it is true that certain vitamins are sensitive to irradiation, the available literature indicates that foods irradiated at levels below 1 kiloGray are not nutritionally inferior to unirradiated foods (51 FR 13376, 13381, April 18, 1986).

The agency is not aware of any information that suggests that low dose (up to 1 kiloGray) irradiation of raw foods causes adverse changes in their physical or sensory qualities that would affect consumer's perceptions as to whether they are raw. Therefore, in the absence of meaningful differences in the appearance and quality between pre- and post-irradiated foods, and in light of the requirement that irradiated foods must be clearly labeled as such, the agency believes that it is appropriate to provide that the term "fresh" may be used to describe foods that have been treated with ionizing radiation at a maximum dose of 1 kiloGray (100 kilorads) in accordance with § 179.26(b) and that otherwise meet the requirements of new § 101.95(a). Accordingly the agency is adding an exemption for treatment with irradiation to new § 101.95(c)(iv).

326. None of the comments objected to the agency's position that use of the term "fresh" is appropriate to describe raw, unprocessed foods that are refrigerated and that otherwise meet the definition of "fresh."

Although refrigeration is a means of preserving food, consumers apparently generally regard raw unprocessed foods that are refrigerated as "fresh" (e.g., "fresh" produce). The agency also believes that consumers are not misled when the term "fresh" is used to describe raw unprocessed foods that are refrigerated. Accordingly, the agency is retaining in new § 101.95(c)(2) the provision that states that a food that meets the definition for "fresh," and that is refrigerated, is not precluded from the use of the term "fresh" under this regulation.

327. Many comments objected to the agency's proposed definition for the term "freshly prepared." Some of these comments pointed out that one of the major limitations associated with the proposed definition of "freshly prepared" is that bakery products (including bread) would not merit use of the term "fresh baked" because, in most cases, it is a common practice for the baking industry to utilize mold inhibitors. Other comments stated that consumers recognize baked bread containing mold inhibitors as "fresh baked" and are not misled by the use of this terminology. Numerous related comments suggested that bread and other bakery products (regardless of whether they contain mold inhibitors), should be permitted to use the term "freshly prepared."

Several comments objected to the provision in the proposal limiting the use of "freshly prepared" to foods available for sale within 24 hours after their preparation or production. Comments stated that the agency has no factual or scientific basis on which to impose a 24-hour restriction for prepared foods to qualify to be labeled "freshly prepared." Comments also stated that the 24-hour timeframe is applied inconsistently across the food industry, is unrealistic, and is impossible for most foods to achieve.

A few comments recommended that as an alternative to the 24-hour timeframe associated with "freshly prepared," the agency should consider timeframes such as 12 hours, 72 hours, 10 days from preparation, or 3 to 7 days, with "freshly baked" meaning those products that are baked within a 24-hour timeframe. A small percentage of comments suggested that any time restriction associated with "freshly prepared" should be based on a product's normal shelf life.

A review of the comments has persuaded the agency to reconsider its proposed definition of "freshly prepared." FDA now recognizes several problems with this proposed definition. First, the comments have persuaded the agency that the 24-hour timeframe proposed for the term "freshly prepared" is impractical and impossible to apply to foods across the board because of the diversity of foods in the marketplace that could be described as "freshly prepared." Additionally, no practical alternatives for defining "freshly prepared" were presented to the agency. To the contrary, because of the wide variety of contexts in which the term could be used to describe foods, FDA doubts that a practical definition for "freshly prepared" that would address all uses of the term is achievable.

FDA has thus reconsidered whether a need exists for a regulatory definition for the term "freshly prepared." First, FDA believes that systematic misuse of terms such as "freshly prepared" is not a significant problem in the marketplace. FDA is not aware of widespread misuse of this term. Further, as stated above, any use of terms such as "freshly prepared" are subject to the requirements of section 403(a) of the act, which prohibits false or misleading labeling. Therefore, the agency has the authority to take action on a case-by-case basis against foods that use the term "freshly prepared" on the label in a manner that is false or misleading. Given these factors, FDA believes that a definition of this term is not necessary to enable the agency to effectively enforce the provisions of the act that forbid false or misleading labeling on foods, and accordingly, FDA is withdrawing the proposed definition for "freshly prepared."

328. Several comments agreed with the agency's longstanding policy that use of the term "fresh frozen" is appropriate to describe a food that is quickly frozen while still "fresh." One comment requested that FDA extend the ***2405** proposed definition for "fresh frozen" to include foods such as " fresh" vegetables that are blanched before blast-freezing.

The agency agrees with the comment that foods blanched before blast-freezing merit use of the term "fresh frozen." Upon review of the literature, FDA finds that the blanching of vegetables before freezing is essential to prohibit the development of off-colors, off-flavors, and other kinds of enzymatic spoilage that are known to develop over a period of time in the frozen product (Ref. 30). Therefore, FDA is including a provision in new § 101.95(b) that provides for use of the term "fresh frozen" on raw foods that are blanched before blast-freezing.

329. Several comments requested that FDA reconsider the provision in the proposal that a food must comply with the definition of "fresh" for the term to be used in its labeling as part of a brand name. Some of these comments expressed the concern that prohibiting the use of "fresh" in brand names would mean banning the use of many brand names and trade names (some that are registered trademarks) that have been used for years in a nonmisleading manner.

The agency has reviewed the comments regarding the use of "fresh" in brand names. FDA is aware that situations exist where "fresh" is employed as an integral part of some brand names. In addition, the agency recognizes that some brand names are registered trademarks, and it is not uncommon for these brand names to be used as part of a company logo or on company promotional material.

The use of the term "fresh" on a food label in any manner, including its use in a brand name, is misleading if the use implies that the food is unprocessed when in fact it has been processed. Further, some of the instances where the term "fresh" has been misused in this regard have involved the use of this term as part of a brand name. For these reasons, FDA concludes that the use of "fresh" as part of a brand name should be subject to the definition it is establishing and is thus retaining reference to the use of "fresh" in a brand name in the introductory paragraph of new § 101.95. If, however, a use of the term "fresh" as part of a brand name does not imply or suggest that the food is unprocessed, and the use is not otherwise false and misleading, there is nothing in this final rule that would prevent this use of the term.

330. A few comments on the use of "fresh" in brand names suggested that FDA should continue to permit the term "fresh pack" on the label of pickles to refer to uncured, unfermented cucumbers packed in a vinegar solution and preserved by either pasteurization or refrigeration. These comments contended that consumers and USDA officials use the term "fresh pack" to distinguish these pickles from brine-cured pickles.

FDA has reviewed these comments. FDA is aware that the term "Fresh Pack" is recognized by USDA to distinguish a certain type of pickles. USDA regulations in 7 CFR 52.1684 specifically state that pickles of fresh-pack type are prepared from uncured, unfermented cucumbers that are packed in a vinegar solution with other ingredients to give the characteristics of the particular type of pickle. They are sufficiently processed by heat for preservation of the product in hermetically-sealed containers. That regulation also identifies characteristics for fresh-pack dill pickles, fresh-pack sweetened dill pickles, fresh-pack sweetened dill relish, fresh-pack sweet pickles, fresh-pack mild sweet pickles, fresh-pack sweet relish, and fresh-pack mild sweet relish, respectively. In recognition of USDA's standards, FDA will not take action against the term "Fresh Pack" when it refers to pickles that are graded according to those standards.

331. Some comments requested that FDA reconsider the provision in the proposal that a food must comply with the definition of "fresh" for the term to be used on its labeling as part of a sensory modifier. Other comments argued that as long as the term "fresh" is not misleading, the agency should permit its use as a sensory modifier, especially in those cases where the term refers to the sensory attributes of a food (i.e., "fresh flavor," "fresh-tasting," "tastes-fresh," "taste

as good as fresh,"). However, a small percentage of comments asserted that the use of "fresh" as a sensory modifier is misleading to consumers and should not be allowed in any product.

FDA has considered these comments concerning the use of "fresh" as a sensory modifier. The use of "fresh" on the label of a food, including its use as a sensory modifier, is misleading if it implies that the food is unprocessed when in fact it has been processed. For this reason, FDA concludes that the use of "fresh" as a sensory modifier should be subject to the definition that it is establishing, and therefore the agency is retaining reference to the use of the term "fresh" as sensory modifier in the introductory paragraph of new § 101.95.

332. Several comments stated that a factual statement such as "spaghetti sauce-made with fresh mushrooms" provides useful information about a food product and should be permitted on the label of a processed food made with a fresh ingredient. One comment suggested that such factual statements should be allowed on frozen foods as well. A few comments contended that an ingredient that has undergone processing is no longer "fresh," and that, therefore, the use of such a statement on a processed food made with a fresh ingredient should be prohibited. The comment said that such a statement would be confusing, meaningless, and misleading to consumers. One comment stated that if "fresh" were defined to mean unprocessed as the agency proposed, it would be inconsistent to allow the term to be used to define an ingredient that had been added to the food before processing.

In the general principles proposal, FDA asked for comments regarding the use of these statements on a processed food because it intended to comprehensively regulate the use of the term "fresh" on food labels. Because the agency is taking a more limited approach in this final rule, it does not believe that it is necessary to specifically address the use of the term "fresh" to describe ingredients used in a processed food in its regulation. The agency concludes that this use of the term can be effectively regulated on a case-by-case basis.

FDA believes, however, that consumers generally are not misled when such statements are made about ingredients used in processed foods, provided that the statements clearly refer to the ingredient and do not imply that the food itself is unprocessed. The agency has not received complaints from consumers about this practice, and most of the comments that mentioned this use of the term said that such statements provide useful information. FDA advises that should specific situations arise where such statements are used in a manner that is misleading, the agency will take regulatory action under section 403(a) of the act.

333. Numerous comments expressed the opinion that the inclusion of blanching as part of a continuous process should not preclude labeling an ingredient as "fresh." These comments stated that blanching does not significantly damage the cellular structure of an ingredient and does not affect the taste of a product. A small number of comments argued that blanched ingredients should not be labeled as "fresh," especially if the entire product is heat-treated after the blanched ingredients have been added to the product.

***2406** FDA notes that blanching, as addressed here, is a common and sometimes required process that is accomplished by subjecting a food to a set temperature for a specific period of time. This practice is used in many food industries to arrest changes in the flavor profile of the food, to expel air and gases to inactivate food enzymes, and to destroy some microorganisms before the food is processed (Ref. 31). FDA believes that when the blanching operation is part of a continuous process, it is not misleading if the label of the processed product contains a statement such as "made from

fresh ——" because the statement functions to inform the consumer of a noteworthy characteristic of the ingredient (i.e., that the ingredient was fresh, not canned, frozen, or dried at the time the food was processed).

334. Many comments both from industry and from consumers, stated that processed products (particularly tomato products) that are made from remanufactured ingredients should include a statement such as "remanufactured," "reconstituted," or "made from concentrate" on the product's PDP to avoid consumer deception and economic fraud in the marketplace. Other comments expressed the view that organoleptic, quality, and structural differences exist between remanufactured ingredients and fresh ingredients, resulting in significant differences in products made from them. Some comments provided data on these differences.

However, numerous comments opposed requiring a declaration on the PDP that a processed product is made from remanufactured ingredients. Some of these comments stated that FDA lacked legal authority and sufficient analytical and scientific data to promulgate a regulation requiring PDP declaration of the use of remanufactured ingredients, and that before the agency suggests that there is a quality difference between remanufactured tomatoes and raw unprocessed tomatoes, this issue would require further investigation. Some of these comments stated that some existing food standards allow for the use of processed ingredients in processed foods without requiring a declaration about the processed ingredient on the PDP. Therefore, these comments asserted, FDA could not require a declaration on the PDP for remanufactured ingredients without proposing to revise some existing food standards. Some of these comments argued that there was no indication in the rulemaking proceedings for the above food standards that consumers are misled by the lack of PDP labeling.

Some comments urged FDA to separate this issue from this rulemaking and to address the labeling of remanufactured ingredients in a separate proceeding after the agency completes implementing the mandatory requirements of the 1990 amendments.

Other comments on this issue argued that, if the agency were to mandate this requirement, it would impose substantial costs on industry. Another comment implied that use of remanufactured ingredients is necessary because it is impossible for manufacturers to meet the demand of tomato-based products using only fresh tomatoes.

The agency has reviewed these comments and concludes that the issue of labeling for remanufactured ingredients involves matters that go well beyond those that the agency raised in the proposal. There is a large amount of information to be evaluated, and any decision on the issue will have a far reaching impact. Because this rulemaking has been conducted under the very tight time constraints of the 1990 amendments, the agency has not been able to fully evaluate all the information that it has received in comments or to develop appropriate provisions for a regulation. In addition, before FDA published the general principles proposal, the California Tomato Packers had submitted a petition (Docket No. 90P-0430) concerning, among other things, declaration of remanufactured ingredients in finished tomato products. This petition includes data and other information and is undergoing agency review.

However, the 1990 amendments do not require that FDA address this issue, and the time constraints in those provisions therefore are not applicable. The agency is persuaded that some of the issues discussed in the proposal concerning remanufactured ingredients warrant further consideration to determine whether labels should be required to inform consumers that processed products have been made with remanufactured ingredients. Accordingly, FDA has

not established provisions in this final rule to address these products. The agency will complete its evaluation of all available information and will take appropriate action separately from this rulemaking. The agency solicits information on differences in finished products made with remanufactured ingredients from those made with unprocessed ingredients. In particular, FDA requests information on whether such differences occur in finished products other than tomato products, and, if so, whether the differences are significant. Information should be identified with Docket No. 90P-0430 and sent to the Dockets Management Branch (address above). If the agency determines that differences in finished products because of the use of processed ingredients are significant, such differences would form the basis for subsequent rulemaking.

In the interim, FDA advises that it has already established labeling provisions that apply to some foods made from processed ingredients. This final rule, in § 101.95, precludes processed products such as tomato products made using remanufactured ingredients from being described as "fresh." In addition, as discussed in comment 334 of this document, processed products made with fresh ingredients may bear label statements stating that fact. The agency will evaluate labels that are not subject to these provisions on a case-by-case basis to determine if they are false or misleading under section 403(a) of the act because they misrepresent a finished product made with a processed ingredient.

335. Several comments stated that extended shelf life foods do not merit use of the terms "fresh" or "freshly prepared." The comments suggested that extended shelf life foods are preserved using modern preservation techniques and should not be given special consideration over other methods of preservation. A small number of comments expressed the view that pasta products that are packaged in modified atmosphere packaging should be able to utilize the term "fresh" as a way to distinguish these pasta products from dried pasta.

FDA notes that "extended shelf life" is a term used to describe a potentially broad class of products in the marketplace. These products include many types of foods, e.g., vegetables, pasta, complete meals; employ many types of preparation and packaging technologies; and are subject to varying degrees of processing. The use of the term "fresh" on extended shelf life foods is subject to new § 101.95 when such use suggests or implies that the product is unprocessed. However, because of the diversity of products in the extended shelf life category, the question of what constitutes processing for such products is not being addressed in this rule and is subject to a case-by-case review by the agency.

336. Some comments suggested that terms that refer to packaging technology (e.g., "freshness seal," "Stay Fresh seal") would be prohibited under the agency's proposed definition for "fresh." These comments suggested that FDA does not have the authority to ***2407** prohibit the use of such terminology as it relates to packaging, specifically in cases where use of these terms are properly qualified. The comments said that such a prohibition would hamper the development of improved packaging technology. Comments also stated that the agency does not have sufficient evidence to suggest that consumers are misled when code dates and freshness guarantees (e.g., guaranteed fresh until) are used on foods. Some comments argued that phrases such as "vacuum packed," "vacuum sealed to lock in freshness," and "for maximum freshness use before a specific date," serve as tools for consumers to distinguish "fresh" product from "stale" product. One comment stressed that vacuum packaging is analogous to blast freezing in that both techniques allow foods to maintain their fresh state.

A small number of comments opposed permitting this use of the term "fresh." Another comment stated that the use of "fresh" in a guarantee statement (e.g., guaranteed fresh) should be restricted and should only be allowed if a food in

question meets the definition for "fresh."

The agency has reviewed these comments and has concluded that the use of terms such as "freshness seal," "guaranteed fresh until," "and vacuum packed to preserve freshness," when they relate only to the function of the package and do not imply or suggest that the food itself is unprocessed, is outside the scope of this rulemaking. FDA acknowledges that these terms are used on numerous food products in the marketplace. To the extent that these terms might be used in any manner that is misleading, the agency will review specific situations on a case-by-case basis under the general misbranding provisions of section 403(a) of the act.

B. Natural

Although the use of the term "natural" on the food label is of considerable interest to consumers and industry, FDA's intent was not to establish a definition for "natural" in this rulemaking. However, the agency did note in the general principles proposal (56 FR 60421 at 60466) that, because of the widespread use of this term, and the evidence that consumers regard many uses of this term as noninformative, the agency would consider establishing a definition. Further, the agency stated that it believed that if the term "natural" is adequately defined, the ambiguity in the use of this term, which has resulted in misleading claims, could be abated. Therefore, the agency solicited comments on several issues that the agency must consider in deciding how to address the use of this term on foods, including: (1) Should the agency establish a definition for "natural" so that the term would have a common understanding among consumers, or should "natural" claims be prohibited altogether on the basis that they are false and misleading? (2) If a definition should be established, how should the agency define "natural?" (3) How should the agency proceed in developing a definition for "natural?" (4) Should a food that is represented as "natural" be considered to be misbranded if it has undergone more than minimal processing (and what constitutes minimal processing?), or if it contains any artificial or synthetic ingredients? In addition, FDA asked that identification of "natural" foods accompany the comments. FDA also solicited comments on how the agency distinguishes between artificial and natural flavors in § 101.22, and on how the agency should provide for a clearer, more appropriate distinction between natural and artificial flavors.

337. The comments provided a wide range of ideas for the agency to consider on the issue of developing a definition for "natural." Some comments stated that the term "natural" should be prohibited entirely on the basis that it generates confusion when used on the label or in the labeling of foods, and that the term is also false and misleading. Some comments stated that the agency should eliminate statements such as: "all natural," "100 percent natural," and made from "100 percent natural ingredients." Some comments suggested that the agency should not consider defining "natural" while it is implementing the mandatory requirements of the 1990 amendments.

Other comments suggested that the agency should address the use of the term "natural" in a separate rulemaking.

Some comments suggested that if FDA does establish a definition for the term "natural," it should encompass those foods that do not contain artificial or synthetic ingredients. A few comments stated that processing should not necessarily preclude a product from being deemed "natural." Other comments stated that the term "natural" and claims for natural ingredients should be permitted, provided that the manufacturer uses the term in a truthful, nonmisleading manner. Comments recommended that the use of natural color ingredients should not be precluded in foods that are

EXHIBIT 31

Food

Draft Guidance: Whole Grain Label Statements

February 17, 2006

Guidance for Industry and FDA Staff

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register.*

For questions regarding this draft document contact Shellee Anderson, Food Labeling and Standards Staff (HFS-820), Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, Maryland 20740, (301) 436-2371 (Updated phone: 240-402-2371), e-mail: shellee.anderson@fda.hhs.gov.

Additional copies are available from:
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U.S. Department of Health and Human Service
Food and Drug Administratio
February 17, 200

Guidance for Industry and FDA Staff[1]

Whole Grain Label Statements

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

This guidance is intended for the regulated food industry and FDA personnel. The purpose of this guidance is to provide guidance to industry about what the agency considers to be "whole grain" and to assist manufacturers in labeling their products.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

Through the years, the Federal Government has worked to provide consistent and scientifically sound recommendations to consumers about healthy eating patterns and wise food choices. Such advice originated with the "Basic Four" and has progressed through today's "Dietary Guidelines for Americans" (developed jointly by the U.S. Department of Health and Human Services and the U.S. Department of Agriculture (USDA)). "Dietary Guidelines for Americans, 2005" (2005 DG) recommends that Americans, amon

other things, "consume 3 or more ounce-equivalents of whole grain products per day, with the rest of the recommended grains coming from enriched or whole-grain products" and that "in general at least half the grains should come from whole grains" (Ref. 1).

Manufacturers can make factual statements about whole grains on the label of their products such as "100% whole grain " (as percentage labeling under 21 CFR 102.5(b)) or "10 grams of whole grains " (21 CFR 101.13(i) (3)) provided that the statements are not false or misleading under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the Act) and do not imply a particular level of the ingredient, i.e., "high " or "excellent source. " In addition, manufacturers may use health claims relating whole grains with a reduced risk of coronary heart disease and certain cancers on their product labels for qualifying foods based on notifications FDA received under section 403(r)(3)(C) of the Act (21 U.S.C. 343 (r)(3)(C)) (health claims based on an authoritative statement of a scientific body) (see FDA Modernization Act of 1997 (FDAMA) Claims[2]). To assist manufacturers in labeling their products in accordance with the Act, the agency has reviewed various industry and scientific definitions of "whole grains" and developed the following questions and answers to provide guidance to industry about what the agency considers to be "whole grain."

III. Definition--Questions and Answers

1. **Question:** What factors should be considered in determining whether a food is a whole grain?

   Answer: Cereal grains that consist of the intact, ground, cracked or flaked caryopsis, whose principa anatomical components - the starchy endosperm, germ and bran - are present in the same relative proportions as they exist in the intact caryopsis - should be considered a whole grain food.

2. **Question:** What are some examples of cereal grains?

   Answer: Cereal grains may include amaranth, barley, buckwheat, bulgur, corn (including popcorn), millet, quinoa, rice, rye, oats, sorghum, teff, triticale, wheat, and wild rice.

3. **Question:** Should soybeans and chickpeas be considered whole grains?

   Answer: Soybeans and chickpeas should not be considered whole grains, but should be considered legumes. Products derived from legumes, oilseeds (sunflower seeds), and roots (e.g., arrowroot) should not be considered whole grains.

4. **Question:** Should a corn flour or corn meal made from corn grain to which the pericarp has been removed be considered whole grain?

   Answer: The four principal parts of a mature corn kernel consist of the hull or bran (pericarp and seed coat), germ, endosperm, and the tip cap (Ref. 2). The tip cap, the attachment point of the cob, may or may not stay with the kernel during handling, and, thus, is not considered an integral part of the kernel or caryopsis. However, the bran, germ and endosperm are integral parts of the kernel and should be present in the relative proportions as found in the kernel to be considered "whole grain." Therefore, for corn flour or corn meal to be "whole grain" it should include the pericarp as well as the other essential fractions.

   We note that there are standards of identity for various types of corn flour and corn meal in 21 CFR Part 137 (i.e., § 137.211, white corn flour; § 137.215, yellow corn flour; § 137.250, white corn meal; § 137.255, bolted white corn meal; § 137.260, enriched corn meals; § 137.265, degerminated white corn meal; § 137.270, self-rising white corn meal; § 137.275, yellow corn meal; § 137.280, bolted yellow corn meal; § 137.285, degerminated yellow corn meal; and § 137.290, self-rising yellow corn meal). Degerminated and bolted corn meals should not be considered whole grain products because germ or bran has been removed during processing. Because the rest of the meal standards allow removal of some of the hull, these also should not be considered whole grain products.

5. **Question:** Barley has a particularly tough hull and is often pearled to make it easier to cook and digest. Can the hull and perhaps a small amount of the bran attached to the hull be removed from barley in the pearling process and it still be considered a whole grain?

   Answer: Most of the barley that is used for food production in the U.S. is of a type in which the kernels are covered with a very tough inedible hull. This outer hull (which covers the bran layer) must be removed before the kernel can be used for human food. The hull on many varieties of barley is strongly attached to the pericarp. Thus, barley is difficult to dehull and generally is pearled. The pearling process abrades away the outer surfaces of the grain with an abrasive surface and removes some of the bran from the barley.

   In general, the barley that is used for human food in the U.S. is pearled. Barley that is pearled should not be considered a whole grain because some of the bran layer has been removed. Dehulled barley should be considered a whole grain because only the tough inedible hull or outer covering has been

removed, but the bran layer is left intact.

6. **Question:** Should rolled oats be considered a whole grain?

   Answer: In the U.S. most oats are flattened to produce rolled oats, or steamed and flattened to create "quick oats." Rolled oats and "quick oats" processed simply by flattening and/or steaming should be considered whole grains because they contain all of the bran, germ, and endosperm of whole oats.

7. **Question:** Does the term "whole grain" mean the same as "100 percent whole grain"? If a product is labeled as "whole wheat bagel" or "whole wheat pizza," how much whole wheat should it contain? What is graham flour?

   Answer: FDA has not defined any claims concerning the grain content of foods. However, the agency has established standards of identity for various types of cereal flours and related products in 21 CFR Part 137, including a standard of identity for "whole wheat flour" (§ 137.200) and "whole durum flour" (§ 137.225). Graham flour is an alternative name for whole wheat flour (§ 137.200).

   Depending on the context in which a "whole grain" statement appears on the label, it could be construed as meaning that the product is "100 percent whole grain." We recommend that products labeled with "100 percent whole grain" not contain grain ingredients other than those the agency considers to be whole grains. Consumers should be able to look at the ingredient statement to determine whether the predominant or first ingredient listed is a whole grain. We note that wheat flou should not be labeled as a whole grain flour because wheat flour is a synonym of flour (§ 137.105), and thus, the bran and germ have been removed. However, whole wheat flour (§ 137.200) should be considered a whole grain flour because it contains all the parts of the grain, i.e., the bran, endosperm and germ. We recommend that pizza that is labeled "whole grain " or "whole wheat" only be labeled as such when the flour ingredient in the crust is made entirely from whole grain flours or whole wheat flour, respectively. Similarly, we recommend that bagels, labeled as "whole grain " or "whole wheat" only be labeled as such when bagels are made entirely from whole grain flours or whole wheat flour, respectively.

8. **Question:** What is durum wheat? Is it 100 percent whole grain? What products are made from durum wheat?

   Answer: Durum wheat is a type of wheat that has a high protein content and the flour has a yellow color. It is typically used for semolina and pastas. Durum flour should not be considered a whole grain flour because the germ and bran have been removed (21 CFR 137.220). However, whole durum flour (21 CFR 137.225) should be considered a whole grain flour because the flour contains all the parts of the grain, i.e., the bran, endosperm, and germ. We recommend that products labeled with "100 percent durum wheat" statements be made entirely with durum flour and products labeled "whole grain" be made entirely from whole durum flour.

9. **Question:** Are there standards of identity for products made from whole grains?

   Answer: There are no standards of identity for whole grain products per se. However, there are standards of identity for whole wheat bread, rolls, and buns (21 CFR 136.180) and whole wheat macaroni products (21 CFR 139.138) which are made from whole wheat flours. For bread, rolls, and buns, the dough is made from whole wheat flour, brominated whole wheat flour, or a combination of these and no other type of flour is used. Whole wheat macaroni products are made from whole wheat flour, whole durum wheat flour, or both.

10. **Question:** What types of label statements about whole grains are currently permitted to be made on food products?

    Answer: Manufacturers can make factual statements about whole grains on the label of their products, such as "10 grams of whole grains," "½ ounce of whole grains," (21 CFR 101.13(i)(3)) and "100% whole grain oatmeal" (as percentage labeling under 21 CFR 102.5(b)), provided that the statements are not false or misleading under section 403(a) of the Act and do not imply a particular level of the ingredient, i.e., "high" or "excellent source."

    In addition, labels may bear a health claim based on an authoritative statement of a scientific body relating whole grains with a reduced risk of heart disease and certain cancers if the food meets the qualifications of one of the notifications submitted under section 403(r)(3)(C) of the Act (see FDA Modernization Act of 1997 (FDAMA) Claims[3]).

11. **Question:** Can the name of the particular whole grain be substituted for the term "whole grain" in label statements? For example, could the statement "100% brown rice" replace the statement "100% whole grains" or "1 ounce whole wheat " replace "1 ounce whole grain?"

Answer: The specific name of the whole grain (e.g., brown rice) can be used for label statements made under 21 CFR 102.5(b) or 21 CFR 101.13(i) (3) as long as the statement is truthful and not misleading. However, "whole grains" is the substance of the health claims established under section 403(r) (3)(C) of the Act and the name of a particular whole grain can not be substituted for the term "whole grain foods" in the health claims.

IV. References

The following reference have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Department of Health and Human Services and U.S. Department of Agriculture, "Dietary Guidelines for Americans, 2005," www.healthierus.gov/dietaryguidelines, 2005.

2. Hoseney, R. Carl, "*Corn*," "Principles of Cereal Science and Technology," St. Paul, MN, 1986.

(1) This draft guidance has been prepared by the Food Labeling and Standards Staff; Office of Nutritional Products, Labeling, and Dietary Supplements; Center for Food Safety and Applied Nutrition at the Food and Drug Administration.

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EXHIBIT 32

RULES and REGULATIONS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 20 and 101

(Docket No. 85N-0061)

RIN 0905-AB67

Food Labeling; General Requirements for Health Claims for Food

Wednesday, January 6, 1993

*2478 AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is adopting general requirements pertaining to: (1) The use of health claims that characterize the relationship of a substance to a disease or health-related condition on the labels and in labeling of foods in conventional food form (conventional foods), and (2) the content of petitions regarding the use of such health claims pertaining to specific substances in such food. This action is being taken in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims for conventional foods. However, in the Dietary Supplement Act of 1992 (the DS Act), Congress imposed a moratorium on the implementation of the 1990 amendments with respect to dietary supplements with only very limited exceptions. Therefore, these final rules do not apply to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances. Elsewhere in this issue of the Federal Register, FDA is issuing final rules that respond, at least with respect to conventional foods and, to the extent that they would permit claims, with respect to dietary supplements, to the 1990 amendments' directive that the agency consider 10 topics associating substances with diseases or health-related conditions. Those final rules have been developed in accordance with the general principles of the requirements in this document.

EFFECTIVE DATE: May 8, 1993, except § 101.9(k)(1) which will become effective February 14, 1994, and §§ 101.14(d)(2)(vii)(B) and 101.14(d)(3) concerning restaurant firms consisting of 10 or less individual restaurant establishments for whom these sections will become effective on May 8, 1994.

FOR FURTHER INFORMATION CONTACT: Victor P. Frattali, Center for Food Safety and Applied Nutrition (HFF-261), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4064.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of November 27, 1991 (56 FR 60537), FDA published a proposed rule to establish general requirements pertaining to: (1) The use of health claims that characterize the relationship of a substance to a disease or health-related condition on the labels and in labeling of both conventional foods and dietary supplements, and (2) the content of petitions regarding the use of such health claims pertaining to specific substances in food. The proposed rule was issued in response to provisions of the 1990 amendments (Pub. L. 101-535) that bear on health claims. With respect to health claims, the 1990 amendments amend the Federal Food, Drug, and Cosmetic Act (the act) by adding a provision (section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B))) that provides that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D).

Congress enacted the health claims provisions of the 1990 amendments to help U.S. consumers maintain healthy dietary practices and to protect these consumers from unfounded health claims. The House Report of June 13, 1990, states, "Health claims supported by a significant scientific agreement can reinforce the Surgeon General's recommendations and help Americans to maintain a balanced and healthful diet" (Ref. 1). Senator Orrin Hatch, one of the primary authors of the 1990 amendments, noted that diet has been implicated as a factor in the three leading causes of death (heart disease, cancer, and stroke) (Ref. 2). In addition, the statement of the House Floor Managers noted that "There is a great potential for defrauding consumers if food is sold that contains inaccurate or unsupportable health claims" (Ref. 3). The House Report characterized the need for regulation as "compelling" (Ref. 1).

FDA's first step in support of the congressional goals of the 1990 amendments appeared in the form of the proposed health claims regulation. The proposed regulation contained: (1) Definitions to clarify the meaning of specific terms used in the regulation; (2) preliminary requirements that a component of food must meet to be eligible to be the subject of a health claim; (3) a scientific standard for assessing the validity of claims both for dietary supplements and for conventional food, general labeling requirements for health claims that are permitted by regulation, and prohibitions on certain types of health claims; and (4) the required content of petitions for health claims.

In response to the proposed rule, FDA received over 6,000 letters, each containing one or more comments, from consumers, health care professionals, universities, State and local governments, foreign governments, trade organizations, consumer advocacy organizations, research institutes, industry, and professional organizations. In addition to receiving these written comments, the agency held a public hearing on January 30 and 31, 1992 (57 FR 239, January 3, 1992), on a number of food labeling issues, including the requirements for health claims. Some of the comments agreed with one or more provisions of the proposed rule without providing further grounds for support other than those presented by FDA in the preamble to the proposal. Other comments disagreed with one or more provisions of the proposed rule without providing specific grounds for the disagreement. A few comments addressed issues outside of

the scope of the regulations and will not be addressed in this document. Most of the comments provided specific grounds in support of their positions concerning provisions of the proposed regulations. The agency has summarized and addressed the issues raised in the sections of this document that follow.

In October 1992, the DS Act was enacted. This statute states that, with certain limited exceptions, the Secretary (and FDA, by delegation) may not implement the 1990 amendments with respect to dietary supplements earlier than December 15, 1993. As a result, this final rule applies only to conventional food (Ref. 34). The DS Act establishes a timetable for the adoption of final rules implementing the 1990 amendments with respect to dietary supplements by December 31, 1993. One exception to the moratorium on the implementation of the 1990 amendments is a provision (section 202(b)) that states that FDA may, earlier than December 15, 1993, approve claims with respect to dietary supplements that are claims described in clauses (vi) and (x) of section 3(b)(1)(A) of the 1990 amendments. FDA is responding to this provision in the documents on the 10 specific substance-disease topics that accompany this final rule.

II. Definitions

FDA proposed definitions for "health claim," "substance," "nutritive value," and "dietary supplement" to serve as tools for clearly establishing the scope of the types of claims that would be ***2479** subject to the regulations promulgated under section 403(r)(1)(B) of the act. In addition, the agency proposed a definition for "disqualifying nutrient levels" to establish limits on the amounts of certain nutrients that are known to increase the risk of disease that can be in a food if that food is to bear a health claim in its labeling.

A. Definition of a Health Claim

As proposed, § 101.14(a)(1) stated:

Health claim means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" endorsements, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include only those statements, symbols, vignettes, or other forms of communication that a manufacturer intends, or would be likely to be understood, to assert a direct beneficial relationship between the presence or level of any substance in the food and a health or disease-related condition.

(56 FR 60537 at 60563)

As was explained in the preamble of the proposal (56 FR 60542), FDA derived this definition almost directly from the provisions of section 403(r)(1)(B) of the act. The proposed definition establishes that a claim must have at least two basic elements for it to be regulated as a "health claim." First, the claim must be about a "substance" as that term is defined in proposed § 101.14(a)(2). Secondly, the claim must characterize the relationship of the substance to a "disease or health-related condition." If a claim has one of these elements without the other, it would not be a "health claim," although it may still be subject to regulation under other provisions of the act (e.g., the requirement of section 403(a)(1) of the act that a label statement be truthful and not misleading).

heartland of America," where no claims about the fat, cholesterol, or sodium content of the food are made).

However, comments from several consumer, health professional, and regulatory organizations demonstrate that the use of the word "heart" in the brand name of a food may lead consumers to believe that the specific food bearing that brand name has properties deriving from a substance that it contains that are beneficial for reducing the risk of developing a disease or health-related condition, specifically cardiovascular disease. Both basic elements of a health claim may be implied in a brand name containing the term "heart." Therefore, any product bearing such a brand name is subject, depending of course on the full content of the labeling, to be viewed by FDA as bearing an implied health claim. Thus, FDA has retained the term "heart" as an example of what may be an implied claim in the definition of "health claim" in new § 101.14(a)(1) to alert firms to the agency's position on this matter. However, FDA will review the context in which this term is presented and consider how the term would be understood in deciding whether a particular use of the term "heart" or a use of a heart symbol on a particular label is a health claim.

3. Other written statements

7. A number of comments suggested that any statement on a label, including nutrient content claims such as the word "healthy" or other terms that may lead consumers to believe that a food has health benefits, should be regarded as implied health claims. Comments suggested that FDA use broad latitude in considering such words as health claims.

As FDA advised earlier in this preamble, the agency will evaluate all of the labeling to determine whether, within the context in which a claim is presented, both basic elements of a health claim are present. Thus, FDA will take a flexible case-by-case approach to assessing whether labeling contains a health claim.

In the case of the word "healthy," the agency does not believe that the use of this word would normally be a health claim. "Healthy" has a wide variety of meanings in addition to ones that would satisfy the second basic element of a health claim. For example, "healthy" can certainly imply general nutritional well-being. Thus, while a claim such as "Eat a diet low in fat for a healthy heart" may be a health claim, "Eating ***2484** five fruits or vegetables a day is a good way to a healthy lifestyle" is not. Moreover, as explained in the document concerning nutrient content claims that appears elsewhere in this issue of the Federal Register, FDA may also regulate the term "healthy" in certain circumstances as an implied nutrient content claim. A proposal on how to define the term in such circumstances appears elsewhere in this issue of the Federal Register. The varied uses of the term "healthy" demonstrate the need for FDA to take a flexible case-by-case approach in deciding whether a claim is an implied health claim.

4. Third party references

8. Some comments requested that FDA explain its interpretation of the term "third party endorsement" and clarify when such an endorsement constitutes a health claim. One comment observed that the courts have been careful not to define the concept of "endorsement" too broadly and noted that disclaimers can be used where the perception of endorsement may be construed. Other comments asserted that the mere presence of endorsements should not automatically constitute health claims. One suggested that regulatory limits concerning such endorsements should be set.

FDA agrees that third party endorsements do not automatically constitute health claims. "Funk & Wagnall's Standard

Dictionary," Harper Paperbacks, New York, 1980, defines the term "endorse" as "to state one's personal support of (a product) to promote its sale."FDA views third party endorsements as references, made through a name or logo, to a person or organization such as a professional society or association that is independent of the product's manufacturer or distributor, on product labeling or advertising, to promote that organization's approval of a product.

In response to the comments addressing the term "third party endorsements," as explained in the agency's response to comment 5 of this document, the codified language of new § 101.14(a)(1) has been revised to refer to "'third party' references." This term, which includes third party endorsements, better describes the type of information from an organization or individual not directly associated with the manufacturer that may be included in a label and that could constitute an implied or express health claim.

Third party references on food labels include a wide variety of information about diet and general health that is disseminated by reputable public or private organizations. Such information will be regulated as a health claim if, within the context of the total labeling, the third party reference can be reasonably understood to characterize the relationship between a substance and a disease or health-related condition. Thus, an endorsement by the American College of Nutrition or the National Nutritional Foods Association would not, of itself, cause a product to be considered to bear a health claim, even if these organizations were promoting the consumption of a specific food or nutrient, if the resultant claim did not include reference to a disease or health-related condition.

However, a third party endorsement would constitute an implied health claim if the endorsement references a particular food or substance, and the name of the endorsing organization references a particular disease (e.g., American Heart Association). In such an endorsement, both basic elements would be present. As a result, a link would be created between the food/substance and the specific disease that could be reasonably understood by consumers as asserting that the product is useful in reducing the risk of developing that disease.

The following illustration using the National Cancer Institute's (NCI's) Five-a-Day Program (Ref. 27) exemplifies how the context of the label will determine whether a statement is a health claim or dietary guidance. A cereal label that says "The National Cancer Institute recommends that you eat five servings daily of fruits and vegetables" is not a health claim because the information cannot be reasonably understood to be about a substance. There is neither a nutrient nor a product-specific element in the claim, and there is therefore no characterization between a substance and the disease included in the name or the organization. However, if the statement said "The National Cancer Institute recommends that you eat five servings daily of fruits and vegetables to increase your intake of fiber," it would be a health claim because of the reference to a specific nutrient, fiber, and to a disease, cancer.

9. Several comments questioned the status of the American Diabetes Association's "Exchange Lists for Meal Planning." One comment questioned the status of the American Diabetes Association's "Self-Test" public awareness program printed on the back of certain cereal boxes, which is designed to enable consumers to recognize diabetes based on warning signs and symptoms of the disease. The comments expressed the belief that these situations should not be interpreted as either an endorsement or a health claim because no claim is made about a specific nutrient in the foods, and no link is created between the products and diabetes. Comments also requested clarification of FDA's position on fund raising activities conducted with the cooperation of manufacturers using organizational logos and messages such as: "A proud sponsor of the American Diabetes Association" or "A contribution from the sale of this

product has been made to the American Diabetes Association."The consensus of these comments was that these situations should not be interpreted as endorsements because no claim is made about the nutrient content of the foods, and there is no association between the products and the disease, diabetes mellitus.

FDA recognizes the value that providing exchange lists on food labeling has for certain consumers and advises that the mere inclusion of that information on a food will not, of itself, subject the labeling to the health claim regime. Reference to the exchange lists lacks the substance element of the "health claim" definition because it relates to many foods rather than to a specific food or a nutrient. Such information is instead subject to section 403(j) of the act and, more specifically, to § 105.67 relating to foods for use in the diets of diabetics. Of course, the labeling would be subject to regulation under section 403(r) of the act if the labeling bears any implication that a substance in the food is helpful in reducing the risk of diabetes or any other disease.

In the absence of an explicit or implied reference to a substance in food labeling, the "Self-Test" program and sponsorship/fund raising information also are outside the coverage of section 403(r)(1)(B) of the act. However, labeling for both of these programs would be subject to section 403(a) of the act, which requires that a label be truthful and not misleading, and section 201(n) of the act which describes the circumstances in which labeling is misleading.

10. Some comments requested that paid third party endorsements be prohibited. These comments stated that such references often give the public the impression that endorsed products are superior in terms of health, safety, or nutrition to other foods not bearing the same endorsement, when, in fact, they are not.

FDA has no authority under the act to prohibit either paid or unpaid third party endorsements or references, provided that, when such statements are included on food labeling, the ***2485** statements are made in a manner that is in compliance with all applicable provisions of the act. However, the agency recognizes that endorsements made for compensation by private organizations or individuals may be misleading to consumers. The agency is advising that when such endorsements are made, a statement should be included in close proximity to the claim, informing consumers that the organization or individual was compensated for the endorsement. Failure to divulge this information on a label that bears a paid endorsement would cause the product to be misbranded under sections 403(a) and 201(n) of the act for failure to reveal a fact that is material.

11. A number of comments suggested that all unpaid endorsements be regarded as explicit health claims.

FDA disagrees, because the issue of whether an endorsement is made in exchange for monetary compensation is not germane to the issue of whether the endorsement or other third party reference constitutes a health claim. As discussed in the response to comment 8 of this document, for a third party reference to be a health claim, two criteria must be met. There must be an implied or explicit reference to both a substance and to a disease or health-related condition. In the absence of these elements, a third party reference is not a health claim, regardless of any financial arrangement that may have been entered into before making the endorsement.

12. Other comments urged FDA to allow the use of third party endorsements of specific products. Many of these comments asserted that references from credible health organizations reduce or eliminate consumer confusion about specific products, provide useful and relevant information about products, and assist consumers in making healthy

food choices. The comments also argued that the use of third party endorsements and references should also encourage the development of new products that attract such endorsements.

FDA has no basis in principle for objecting to the use of third party endorsements and other third party references for specific products, provided that such references are made in compliance with all applicable provisions of the act, including the nutrient content claims and health claims requirements of the 1990 amendments and sections 403(a) and 201(n) of the act. The agency is aware of the potential impact of the 1990 amendments on the development of more healthful products that will appeal to consumers and encourage people to improve their eating habits. In the Congressional Record of October 24, 1990, Senator Hatch (Ref. 2) stated:

* * * manufacturers should have the economic incentives they need to be creative and innovative so that more and more low-fat, reduced sodium, and high-fiber foods come into the market. We should not deter such benefits for the consumer.

FDA is very much in favor of product innovation as a means of bringing more healthful products to the American public and recognizes that appropriate and lawful third party endorsements may have some potential to stimulate innovation and play a useful role in educating consumers about the importance of developing diets that will improve their health.

13. A number of comments recommended that FDA selectively designate which governmental and nongovernmental organizations are allowed to make third party endorsements. One comment suggested that FDA require organizations that grant endorsements to have the expertise in the area in question as well as a formal product approval process. The organization should actively disseminate additional explanatory information concerning the meaning of the endorsement and manner of its use. Other comments recommended that third party endorsements be considered to be misleading unless the reason for the presence of the endorsement is clearly explained (including but not limited to disclosure of financial arrangements).

With the exception of disclosing the fact that an endorsement has been paid for, as discussed in comment 10 of this document, FDA believes that it lacks the factual and legal basis at this time for imposing such requirements on third party endorsements. FDA recognizes, however, that third party references have significant potential to be abused or to be misleading if, for example, they come from organizations or programs that exist primarily for commerical or marketing purposes, they are not based on sound nutritional criteria, or they appear on products that are not appropriate in light of the actual or implied nutritional purpose underlying the endorsement. Therefore, the agency will closely monitor the use of endorsements on food labels. Interested persons should submit their views on the need for additional regulatory controls to the Center for Food Safety and Applied Nutrition. FDA intends to consider in a future rulemaking proceeding whether additional criteria or controls are necessary.

In the meantime, any labeling generated with a third party endorsement or reference would be subject to regulation under sections 201(n) and 403(a) of the act and must, therefore, be truthful and not misleading. Further, if the reference meets the definition of a nutrient content claim or a health claim, such a claim must be consistent with FDA's regulations.

14. A number of comments suggested that all written health claims be banned in favor of third party endorsements. One of the comments favored allowing third parties, such as the American Heart Association and the American Dental Association, to independently review products and to place their logos on the labeling if they determine that use of the product would be helpful in reducing the risk of their specialty disease.

FDA has an obligation under the act to ensure that health claims comply with section 403(r) of the act, and that they are truthful and not misleading under section 403(a). Delegation of this responsibility to private organizations associated with specific diseases would not be consistent with the act. Such organizations are free to submit well-supported petitions pertaining to the health benefits of any substance to FDA, as provided for in new § 101.70. However, FDA will always have the obligation of ensuring compliance with the act.

5. Symbols

In the preamble to the proposed rule (56 FR 60537 at 60542), FDA recognized that there is often ambiguity in the message conveyed by a symbol or logo and solicited comments on the appropriate meaning to be attributed to a heart symbol and other currently used logos and symbols. The agency also invited comments on the issue of how logos should be regarded: as nutrient content claims, health claims, or both? The comments, which are summarized below, ranged from those that wanted strict regulation of symbols to those that felt symbols should not be regulated as health claims. Many comments took an intermediate position, arguing that symbols should be evaluated within the context of total labeling.

15. Many comments supported FDA's proposal to regulate symbols as health claims. These comments stated that the uncontrolled use of medical symbols (e.g., a heart or an electrocardiogram (EKG)) should not be permitted. Some comments suggested that symbols be allowed only when the food qualifies for the health claim implied by the symbol, and then only if they are not misleading ***2486** and increase consumers' comprehension of the claim.

Many industry comments argued that symbols cannot practicably be included in the definition of a health claim. One comment pointed out that candy packages bearing a heart symbol near Valentine's Day should not be regulated as an implied health claim. Another comment cited examples where the heart symbol may do nothing more than operate as a design motif with no implicit health claim (e.g., the combination of a heart symbol plus the statement "Hey Fudge Lovers! More Fudge Filling!"). The comments maintained that any analysis of how the symbol is construed must focus on the entire label, not on an isolated aspect of it.

FDA agrees that a determination as to whether a symbol constitutes a health claim must be made based on the entire food label. As explained in the response to comment 5 of this document, FDA has provided for such flexibility by revising new § 101.14(a)(1) to state:

Implied health claims include those statements, symbols, vignettes, or other forms of communication that a manufacturer intends, or that would be reasonably understood in the context in which they are presented, to assert a relationship between the presence or level of a substance in the food and a disease or health-related condition.

"Funk & Wagnall's Standard Dictionary" defines the term "symbol" as "something chosen to represent something